

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION
Case 01-4319-CIV-KING

SYLVIA ALLEN,

Plaintiff,

vs.

MIAMI, FLORIDA

R.J REYNOLDS TOBACCO COMPANY,
and PHILIP MORRIS INCORPORATED,

FEBRUARY 25, 2003
TUESDAY - 9:00 A.M.

Defendants.

MORNING SESSION

TRANSCRIPT OF JURY TRIAL PROCEEDINGS
BEFORE THE HONORABLE JAMES LAWRENCE KING,
UNITED STATES DISTRICT JUDGE
VOLUME 1A

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1 MORNING SESSION
2 THE COURT: Thank you. It has been brought to my
3 attention that we had talked about having a charge conference
4 this afternoon. Let me inquire as to the status of the defense
5 case at this point. I don't wish to interrupt it if you have a
6 doctor here from out of town or out of country.
7 MR. REID: I think we can finish the witness and then
8 have the charge conference late this afternoon, and we are
9 working with Mr. Perwin as we said we would.
10 THE COURT: About what time do you feel is appropriate
11 to have the charge conference?
12 MR. REILLY: Your Honor, I don't know exactly how long
13 cross-examination of this witness will take. My direct of the
14 next witness will probably take an hour, maybe a little longer.
15 THE COURT: So we are looking at 3:00 or 4:00 or 5:00
16 or something? I hate to start the charge conference at 5:00.
17 MR. REID: 3:00.
18 MR. REILLY: Well, I don't want to hold the witness
19 over for another day for the charge conference. I don't think
20 it should take that long to put the witness on, so 3:30, 4:00,
21 so I would think that's highly probable.
22 MR. COHEN: Our expectation, Judge, is that we would
23 be able to meet that time frame, 3:30, 4:00, charge conference.
24 MR. REID: I will have somebody call Joel.
25 THE COURT: All right. Also let me announce that with
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1 respect to the motions for directed verdict that have been

2 made, Rule 50 motions, at the conclusion of the plaintiff's
3 case, that I have reviewed a great number, perhaps most if not
4 all, of the cases that have been referred to me and I have
5 reviewed my notes on your argument. I have concluded that
6 sufficient evidence has been presented to submit this matter to
7 the jury. The motions are denied.

8 I reviewed and considered last night the motion to
9 strike that was filed by the plaintiff regarding the portion of
10 the testimony of Lacy Ford given February 19, 2003 and the
11 defendant's response thereto, and concluded that that motion
12 should be and is denied.

13 The parties will only be able to argue to the jury
14 what is a matter of record, not argue confusion or anything.
15 But if that comes up, it would be subject, and I don't think it
16 will, I don't think anybody's going to argue -- I am sure no
17 one's going to argue -- that the confusion that the plaintiff
18 apprehends will be argued to the jury as a matter of fact or a
19 matter of actual status of the record. If it does, we can deal
20 with it at that time and/or it can be argued in rebuttal or a
21 jury instruction can be done at that time.

22 All right. Bring in the jury.

23 [The jury returns to the courtroom.]

24 THE COURT: Thank you. Be seated, please.

25 Let's see, I believe when we recessed we had Doctor
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7

MANYAK - Cross

1 Manyak. Is he available?

2 Would you please step up. We have reached the point
3 that we are about to commence cross-examination. Doctor, you
4 are reminded that you are under oath.

5 Mr. Cohen for the plaintiff.

6 CROSS EXAMINATION

7 BY MR. COHEN:

8 Q. Doctor, I am Jay Cohen. I represent Sylvia Allen.

9 Doctor, yesterday you talked a little bit with the
10 jury about the spread of cancer and the pattern of disease. Do
11 you recall that?

12 A. Yes, sir.

13 Q. What you told the jury was about how a kidney cancer can
14 spread to other organs and other systems of the body through
15 the lymphatic system, the drainage system as you described it,
16 or the blood system, correct?

17 A. Yes, sir.

18 Q. Is the opposite also true?

19 A. What do you mean by that?

20 Q. Can cancers of other organs spread through the lymphatic
21 system and through the blood system to the kidney?

22 A. Yes.

23 Q. So a lung cancer, if it's primary, can spread from the lung
24 via one of those two routes and attack the kidney?

25 A. Yes.

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MANYAK - Cross

1 Q. Can a lung cancer spread via one of those two routes and
2 attack the other bones of the body?

3 A. Well, it would be primarily through the blood route to go
4 through the bones as it would be with other cancers.

5 Q. So, for example, you are familiar with the spread of lung
6 cancer to the spine?

7 A. I don't study or deal with lung cancer on a routine basis,
8 but in general, yes, I am familiar with that concept.

9 Q. It can spread to the skull?

10 A. It can.

11 Q. It can spread to the liver?
12 A. It can.
13 Q. To the kidney?
14 A. It can.
15 Q. That's what we have been calling metastatic spread?
16 A. A spread from a primary site to a secondary site is
17 metastatic spread.
18 Q. Can a cancer in an organ spread within itself in that
19 organ?
20 A. It can on occasion, depending on the organ system. That is
21 thought to be possible in certain organ systems. It depends.
22 The question in many pathological circles is whether or not
23 there is internal spread or whether there are secondary
24 primaries that arise. That's a matter of debate as far as my
25 understanding of pathological process is concerned.

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9

MANYAK - Cross

1 Q. That's an interesting concept that you just talked about
2 and I was going to ask you.
3 What is a second primary site? What does that mean in
4 cancer?
5 A. It means there is a second site with another cancer that
6 arises there.
7 Q. So there is even occasions in which there can be a primary
8 cancer in one organ and then a second primary cancer in another
9 organ?
10 A. It's very rare, but it can happen, yes.
11 Q. Have you ever heard of the axiom "there are no rules
12 concerning cancer?"
13 A. I am not sure that I would abide by that. There are
14 certainly many rules about cancer. In fact, the definition of
15 cancer follows a set of rules.
16 I think that many things can happen with cancer, if
17 that's the point you are trying to make.
18 Q. Do you know a Doctor Steven De Prima?
19 A. I do not.
20 Q. Do you know a radiologist who was called by the defendant
21 cigarette companies in this case?
22 A. I don't know any of those radiologists.
23 Q. Did you read any trial testimony?
24 A. I believe I read Doctor Nadji's testimony.
25 Q. You read Doctor Nadji's trial testimony from this case?

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10

MANYAK - Cross

1 A. Yes, yes.
2 Q. Did you ask for that?
3 A. No.
4 Q. It was provided to you?
5 A. Yes.
6 Q. By the lawyers representing the cigarette companies?
7 A. Yes.
8 Q. Do you know why?
9 A. Well, I presume that they wanted me to read the testimony
10 to see what the comments were regarding his particular area of
11 testimony.
12 Q. Did you need that?
13 A. I don't know. It didn't change my opinions at all. So I
14 certainly didn't need it. But when you are in these situations
15 and people ask you to read things, you generally read them.
16 Q. But you didn't ask for it?
17 A. No, I did not.
18 Q. Did you read any other trial testimony?
19 A. I don't believe so, sir.

20 Q. Were you told about any of the trial testimony that has
21 gone on in this case?

22 A. Not really. Maybe a comment here or there, but no
23 substantive discussion about what's going on here.

24 Q. You came into town when, Doctor Manyak?

25 A. Sunday night.

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11

MANYAK - Cross

1 Q. Had a chance to meet with the lawyers for the cigarette
2 companies that hired you?

3 A. I met with them briefly, yes.

4 Q. Is that when Doctor Nadji's trial testimony was given to
5 you?

6 A. No, it was sent to me I think about two days before that.

7 Q. So while you were still in your hometown?

8 A. Yes.

9 Q. Doctor Manyak, one of the reasons you gave this jury
10 yesterday was that you thought that this was a renal cell
11 carcinoma was due to some of the treatment that Mr. Allen
12 received in his last hospitalization, correct?

13 A. That's one piece of evidence, yes.

14 Q. You would agree that what you were talking to him about was
15 the IL-2 treatment, or the IL-2 course of treatment, that
16 Mr. Allen was given in that last hospitalization?

17 A. Yes, that was the component therapy that we were talking
18 about.

19 Q. IL-2 is interleukin-2?

20 A. Yes.

21 Q. Today there is even new phases of interleukin, correct?

22 A. There are several types of interleukin. The protein is
23 involved in a inflammatory cascade. Interleukins have various
24 actions. IL-2 is being looked at for use in cancer, but some
25 of the other ones are as well.

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MANYAK - Cross

1 Q. You are certainly familiar with IL-2. As you told the
2 jury, you believe that is an immunotherapy, not a chemotherapy,
3 but an immunotherapy that is used to treat kidney cancers?

4 A. That actually falls in a category of biological response
5 modifiers. That is, in essence, what an immunotherapy is. It
6 alters or effects the immune system in some fashion.

7 Q. You told the jury you reviewed the medical charts and
8 records in this case, correct?

9 A. Yes, sir.

10 Q. In particular you would have reviewed the last
11 hospitalization, being -- assume with me it's August 24, 1999,
12 until the date of his death, October 1, 1999, correct?

13 A. I reviewed it originally, yes.

14 Q. Can we look at some of those records together that you
15 reviewed?

16 A. Certainly.

17 Q. I have what is called an Elmo up here.

18 A. Does this mean I don't need to use my glasses?

19 Q. I hope that's true, and I can even zoom in it for you.

20 One of the things that you discussed with the jury
21 yesterday when you were looking at some of his records was the
22 discharge summary. Do you remember that?

23 A. Yes.

24 Q. I believe, if I am not mistaken, there was a blowup of that
25 that Mr. Cesarano and you went through, correct?

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13

MANYAK - Cross

1 A. Yes, sir.

2 Q. Doctor, although you indicated that this was a discharge
3 summary, but it's really an expiration summary. You know that
4 term, correct?
5 A. I am not familiar with the term "expiration summary." We
6 speak of death certificates and discharge summaries. I am not
7 familiar with expiration summaries, per say, as the term, but I
8 will accept that, whatever you mean by that.
9 Q. Fair enough. Discharge summary is fine. In any event,
10 this was signed and dictated October 13th of 1999, correct?
11 A. That's what the date says. I see a date of October 1st
12 here.
13 Q. That was the expiration date. That means the day he died,
14 correct?
15 A. Correct. I don't see any other date that tells me when
16 this was dictated.
17 Q. Let me show you on this page.
18 A. I see it there, dictated date.
19 Q. Going back to the first page, you saw, when you reviewed
20 this chart, that at least at the time of his admission, that is
21 when he is admitted by his primary physician, his attending
22 physician, the admitting diagnosis was lung cancer, correct?
23 A. Yes.
24 Q. When he died, the death diagnosis was lung cancer, correct?
25 A. According to this document, yes.

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MANYAK - Cross

1 Q. With respect to the history, what you told the jury
2 yesterday was that the reference to a kidney cancer as
3 indicated under history is that in the past it was undecided
4 whether it had originated in the kidneys or the lung, correct?
5 A. Yes.
6 Q. So as of the date of this discharge summary, a fair reading
7 of this is that the patient died from a lung cancer that was
8 terminal, correct?
9 A. It's incorrect, because I believe they missed the
10 diagnosis. They are consistent with their inaccuracy, yes.
11 Q. They are wrong?
12 A. Yes, they are.
13 Q. Let's see what else you told the jury. Getting back to the
14 issue on the interleukin-2, and one of the reasons and one of
15 the bases for your opinion was this course of treatment. Did
16 you look at this record when you reviewed the charts and
17 records of Bob Allen?
18 A. Yes.
19 Q. You can certainly know that this is pharmacy orders that
20 are typical in every hospital, orders entered by physicians,
21 correct?
22 A. It's the type of pharmacy order used by this particular
23 hospital. It varies from hospital to hospital, but essentially
24 it's just another type of form.
25 Q. You are familiar at least with respect to that form, that

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15

MANYAK - Cross

1 you may have a different form, but these are the type of orders
2 that doctors even like yourself at George Washington University
3 -- by the way, is that a UHS facility?
4 A. I don't know what you mean by that. You mean is it owned
5 by UHS?
6 Q. Yes.
7 A. The hospital is, but the university is not. The university
8 is separate. They work together in the medical center.
9 Q. In your facility, you may have a different form, but you
10 certainly have orders that you enter where you order the

11 appropriate drugs or regimen of drugs or therapy for your
12 patients?
13 A. That's correct.
14 Q. Would you agree that under number ten that's highlighted
15 here, this is the order for the IL-2?
16 A. That's what it looks like, yes.
17 Q. Tell the jury for what period of time the dosage and the
18 duration for this order.
19 A. The dosage, as listed there, as everybody can see, at so
20 many units, grams, usually given per surface area of the body,
21 it's said to be given over twelve hours, and continues infusion
22 for four days for a total of two liters.
23 Q. Intended, obviously, for a regimen of four days?
24 A. That's what it appears to be, yes.
25 Q. Do you know the duration, the dosage, the appropriate

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16

MANYAK - Cross

1 acceptable regimen for IL-2 therapies in kidney cancer
2 patients?
3 A. I do not administer chemotherapy or immunotherapy of this
4 type, intervenous. I am familiar from the standpoint of what
5 the variable dosages and length of treatment is for an
6 individual cancer.
7 I am familiar that it's variable depending on how the
8 patient responds and what their side effects are.
9 Q. Yesterday, when you were talking with the jury about IL-2
10 and about treatment modalities for kidney cancer, you don't do
11 that?
12 A. No, medical oncologists are the ones that administer those
13 drugs. It would be highly unlikely for a urologist to
14 administer interleukin-2.
15 Q. Are you a kidney cancer specialist?
16 A. I am a urologic oncologist which deals with kidney cancer,
17 yes. If you know something about the management of cancer, you
18 realize that there are several people involved with the therapy
19 of cancer. The specialty that primarily deals with medical
20 infusion of chemotherapy and things like immunotherapy are the
21 medical oncologists. It's part of a team approach to the
22 management of cancer. They are an integral part as well.
23 Q. In any event, you do not get involved in the medical
24 oncology for treatment of a kidney cancer?
25 A. I do not administer the drugs. I am involved in the

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17

MANYAK - Cross

1 decision process with the physicians. Nor would they, in turn,
2 remove the kidney by surgery. That would be my part of the
3 business.
4 Q. I take it with respect to this entry and Mr. Allen's
5 medical charts and records, do you even know whether or not
6 that is an appropriate and therapeutic treatment regimen for
7 interleukin-2 on a kidney cancer, or a suspected kidney cancer?
8 A. It is certainly in the range of the type of administration
9 that would be given. But can I tell you what the specific
10 amounts and times are? No I can not. That is not my area of
11 expertise.
12 Q. Are you familiar with the side effects of interleukin-2?
13 A. I am.
14 Q. You know that as a result of the administration of an
15 interleukin-2, some patients can get a dermatitis or rash,
16 correct?
17 A. They get many side effects from this type of medication.
18 Q. They could get a mucositis, correct?
19 A. I believe so.

20 Q. Do you know what that is?
21 A. I know what a mucositis is. I honestly don't know if they
22 can or not get a mucositis, to be honest with you. What they
23 get is a syndrome, like a shock-like syndrome, where you have a
24 multiple of things that go on. High fevers, vascular -- the
25 integrity of the vessels is changed so that fluid leaks across

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18

MANYAK - Cross

1 the veins and vessels. Fluid fills up lungs. There are
2 problems with cardiac output in blood volume to circulate, and
3 a variety of things like that. In that respect, I know what
4 IL-2 does.

5 As far as each specific side effect in the percentage
6 of occurrences that occur, I am not -- I am not comfortable
7 with trying to discuss that part.

8 Q. At the very least, you know that there are possible side
9 effects including skin manifestations?

10 A. I am sure there might be, certainly. I am familiar with
11 the shock-like syndrome. I have seen it personally in patients
12 when I was at the National Cancer Institute. But I am not
13 familiar with all the myriad side effects that can occur with
14 this systemic medication

15 Q. When you were looking at Mr. Allen's last admission at the
16 Sylvester Cancer Center Hospital, did you see on this record,
17 the day after the administration, or I should say the order for
18 administering interleukin-2, that there were some other entries
19 concerning that medication?

20 A. I am sure I read this at one time, yes.

21 Q. On the top part, on August 28, the day after the record we
22 just saw, there was some verification needed concerning his
23 interleukin-2 dose, right?

24 A. Well, that's what has been ordered. I don't know what that
25 entails exactly.

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19

MANYAK - Cross

1 Q. You see on the bottom, "8/29/1999?"

2 A. Yes.

3 Q. Did you see that entry?

4 A. I did at one time, yes.

5 Q. All right. So you acknowledge that by the next day, that
6 is, on the 29th, there was a concern about some reaction that
7 Bob Allen was getting to the interleukin-2, correct?

8 A. Yes.

9 Q. There was a record entry by Bob Allen's doctors concerning
10 decreasing the IL-2, and if he continued to have itching
11 symptoms or other symptoms, it was to be discontinued, correct?

12 A. It's very common with this medication.

13 Q. What does that mean when a doctor writes that if something
14 continues, it is to be discontinued? What does that mean?
15 What does the discontinuing referring to?

16 A. That would be to stop the medication.

17 Q. And you saw this?

18 A. I saw the order, yes.

19 Q. Did you see this document, the very next day in the same
20 medical chart and records of Bob Allen that you reviewed?

21 A. Yes.

22 Q. So by August 30, the very next day, that IL-2 was stopped,
23 wasn't it?

24 A. It looks like it was held on August 30, where it says,
25 "continue to hold IL-2, yes.

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20

MANYAK - Cross

1 Q. Where it says "continue to hold IL-2," if they are reading

2 as a doctor who is familiar with charts and records, that meant
3 it had been held previous to that entry and was continuing to
4 be withheld from administration to the patient?
5 A. It appears that the day before they stopped it. They made
6 a judgment that day to continue to hold giving the medication,
7 yes.
8 Q. Later that day, August 30, 1999, you see a record where
9 they were to resume with some infusion, correct?
10 A. Yes, after the above medications had been given.
11 Q. Right, and the above medications included were Benadryl,
12 correct?
13 A. Yes.
14 Q. He was having this reaction to the IL-2. They were trying
15 to give him some medications. In the interim, they stopped
16 giving him IL-2, correct?
17 A. For a short period of time, yes, that's what it looks like.
18 Q. For a short period of time.
19 Did you see, Doctor, this record. By September 1,
20 1999, after the IL-2 had been started, stopped, maybe restarted
21 again, did you see by September 1, 1999, that they had stopped
22 giving Bob Allen IL-2, interleukin, for the alleged treatment
23 of his kidney cancer?
24 A. Yes, but they didn't stop it because of the effectiveness.
25 They stopped it because of the side effects. It's very common

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21

MANYAK - Cross

1 with this medication. It's very, very tough stuff.
2 Q. Doctor, did you look at the MAR from his hospital records?
3 A. Could you please tell me what MAR means?
4 Q. Medication administration record.
5 A. I am sorry. Ask me the question again.
6 Q. The medication administration record.
7 A. What did you ask me about it?
8 Q. Did you see his MAR, his medication administration record?
9 A. I probably did. I would have to see it again. If you want
10 me to refer to it, I would be happy to look at it again.
11 Q. Absolutely, Doctor.
12 A. Thank you.
13 Q. If you could, sir, what I have handed in front of you is a
14 package of the MAR, the medication administration record, for
15 Bob Allen for his last admission at the Sylvester Hospital. I
16 have some highlights in there. I have got a couple of tabs.
17 At the very least, if you would, can you tell the jury when it
18 was that Mr. Allen had received his last interleukin dose?
19 A. Well, do you have a tab that points that out for me?
20 Q. Yes, sir.
21 A. That would save me a lot of time. Which tab would that be?
22 Q. The last tab.
23 A. All right. It looks like the date on this appears to be
24 8/30, 8/28.
25 Q. So when was it, 8/28 or 8/30?

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22

MANYAK - Cross

1 A. Well, I am reading here -- I'm trying to read through the
2 handwritten stuff as well. It's really kind of unclear to me
3 on this record, but it appears that it's ordered to start on
4 8/28, ordered to stop on 8/31. It appears that he received his
5 last dose on 8/31 because it's initialed here as -- it looks
6 like it's initialed here that he received it sometime on 8/31.
7 I am not sure when exactly.
8 Q. Can we at least agree that on 8/31 was, at the outset, the
9 last time that on that sheet he would have received any
10 interleukin-2? And I invite you to go through the rest of the

11 records.
12 A. That's fine. I will accept that if that's what you are
13 trying to tell me. It appears that you are correct there.
14 That would match with the orders, too, so that would be
15 consistent.
16 Q. Doctor Manyak, this was a failed IL-2 attempt at treatment,
17 wasn't it?
18 A. I wouldn't say it was failed. It was stopped for other
19 reasons. It was failed because of side effects. It wasn't
20 failed because of the failure to be effective. It was an
21 aborted full therapeutic regimen.
22 Q. Did you review this record by Doctor Sridhal on September
23 13, 1999 when he talked with the family about Bob Allen's
24 progression of his cancer, and he also spoke to them about the
25 failed IL-2 treatment?

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23

MANYAK - Cross

1 A. IL-2 is given in a series of courses. A full IL-2 course,
2 if I understand correctly, would involve more than one series
3 of infusions. Because he had these side effects that were
4 intolerable, I believe that would be the basis for saying there
5 was a failed therapy with IL-2. It doesn't mean it wasn't
6 effective. It means he couldn't continue with it because of
7 the side effects.
8 Q. He was never able to reach a therapeutic level for IL-2
9 because the treatment failed as a result of his reactions, and
10 he never received that subsequent course of therapy that you
11 just told the jury about, correct?
12 A. I am not sure I agree with that. In one sense, it's failed
13 because he didn't get four different regimens on it. In
14 another sense, he did get a full regimen of the first set of
15 infusions. If you were splitting some hairs here, but yes, it
16 was failed because he didn't get all four regimens or how many
17 courses they wanted to give him. Again, that's a very common
18 thing with this medication. I will concede it's failed. I
19 have no problem with that.
20 Q. At the very least, Doctor, you agree that this failed
21 attempt on IL-2 therapy, therefore, had no affect on reducing
22 the size of his chest lesions, his chest tumors, his metastatic
23 spread, correct?
24 A. No, I am not so sure I agree with that. As I testified
25 yesterday, when we looked at the CT scan of the chest, at the

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24

MANYAK - Cross

1 very least, while other tumors were growing in the past, these
2 tumors in the chest had stabilized over that time. In the
3 medical oncology circles and in our circles also, stabilized
4 disease suggests some kind of response in the face of something
5 that's rapidly progressive and growing.
6 I am not so sure. Again, that's many pieces of
7 evidence about renal cell carcinoma. Frankly, it's the one
8 that I least rely on for my comments about the fact that this
9 is a kidney cancer.
10 Q. I take it, then, you would at least agree that that would
11 be, in the role of prominence, that's the least prominent basis
12 for your opinions?
13 Frankly, I expect him to fail from IL-2 with kidney
14 cancer. Only about fifteen percent actually have a response.
15 The fact that anything was seen is surprising and actually a
16 sign that there may have been some effect. Frankly, there is
17 nothing very good from chemotherapy or immunotherapy for kidney
18 cancer.
19 Q. Were you familiar, in looking at the chart and the records

20 of Bob Allen, about the treatment he had received prior to his
21 last admission when interleukin-2 was administered?

22 A. I don't recall that he had interleukin-2 administered
23 before this admission.

24 Q. No, no, I am not asking you before. This first
25 administration of interleukin-2 during this last

SYLVIA ALLEN vs RJ REYNOLDS/P.MORRIS - 2/25/03

25 MANYAK - Cross

1 hospitalization, are you familiar, did you review other records
2 and note what kind of treatment he received from other doctors
3 for his lung cancer?

4 A. I know he received chemotherapy. I don't remember which
5 medications those were. Those were a regimen that are used for
6 lung cancer.

7 Q. Did you know that Doctor Markoe, in your review of records,
8 also provided radiation treatment?

9 A. Yes.

10 Q. Doctor, let me turn a little bit to some discussions you
11 had yesterday to the jury about cigarette smoking and kidney
12 cancer.

13 A. Are we finished with this record here? Would you like to
14 take it back?

15 Q. Yes. First of all, and before I get into some of the
16 medical literature and research that you told the jury you did
17 with respect to this case, have you ever published anything
18 with respect to cigarette smoking and kidney cancer?

19 A. No.

20 Q. Have you ever published anything with respect to cigarette
21 smoking and lung cancer?

22 A. No.

23 Q. Have you ever testified before in a court, whether it be
24 this state or any other state, concerning cigarette smoking and
25 kidney or lung cancer?

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26 MANYAK - Cross

1 A. No, I have not.

2 Q. The majority of your publications or whatever you have done
3 deals with prostate cancer or bladder cancer when dealing with
4 cancer?

5 A. Most of them, yes. I have I think three publications on
6 unusual kidney cancers that we have published. We do a lot of
7 work with prostate cancer and bladder cancer as well. Those
8 are areas that I published in, yes.

9 Q. Sir, did I understand yesterday you told the jury that you
10 do not believe there is a causal link between cigarette smoking
11 and kidney cancer?

12 A. Yes, that's correct. Kidney cancer arises, renal cell
13 carcinoma. We separate the two and we are talking kidney
14 cancer, we have to discuss either a transitional cell and renal
15 cell carcinoma.

16 Q. We will talk about the difference between renal cell
17 carcinoma and transitional cell in a second. Your practice of
18 urology, is that part of the internal medicine field?

19 A. No.

20 Q. Do you consider yourself an internal medicine physician?

21 A. No.

22 Q. Are you familiar with publications in internal medicine
23 that deal with cancers of the kidney or kidney disease?

24 A. When you say internal medical literature, that encompasses
25 a lot of things. There are articles in epidemiology and other

SYLVIA ALLEN vs RJ REYNOLDS/P.MORRIS - 2/25/03

27 MANYAK - Cross

1 things that I am familiar with, but certainly, I am not

2 familiar with all the internal medicine literature on renal
3 cell cancer. That's something that they don't often write
4 about.
5 Q. You have talked a little bit with the jury about some of
6 the research that you looked at and some of the studies that
7 you've done, and/or your own contributions in medical
8 literature. Are you familiar with Harrison's Principles of
9 Internal Medicine?
10 A. That's a textbook for internal medicine, yes.
11 Q. Probably in your office?
12 A. Probably not.
13 Q. Published in twelve or thirteen languages across the world?
14 A. Very possibly. It is a well-known internal medical
15 textbook, and one that I used when I was in medical school.
16 Q. Do you agree, Doctor Manyak, that each year primary
17 carcinoma of the lung affects ninety-nine thousand males and
18 seventy-eight thousand females in the United States?
19 MR. REILLY: Objection, Your Honor. He hasn't
20 identified him as an authoritative source in his field or in
21 this field.

22 THE COURT: All right. Do you know, Doctor,
23 approximately how many people in numbers are affected by the
24 disease or diseases that he referred to?

25 THE WITNESS: With cancer of the lung, it's
SYLVIA ALLEN vs RJ REYNOLDS/P.MORRIS - 2/25/03

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MANYAK - Cross

1 approximately one hundred ninety thousand patients a year, from
2 the cancer statistics that are compiled every year.
3 Approximately, yes. I am not an expert in lung cancer, so, you
4 know.

5 BY MR. COHEN:

6 Q. That's why I'm just asking if you know. Do you know that
7 the large majority of lung cancers are caused by carcinogens
8 and tumor promoters ingested via cigarette smoke?

9 MR. CESARANO: I object. It's beyond the scope of
10 direct. We didn't discuss primary lung cancers in this
11 fashion, and I object.

12 THE COURT: Well, I think you can introduce those or
13 have them introduced in other phases. Testing his knowledge in
14 the area, he said that he was not a specialist in lung cancer.

15 BY MR. COHEN:

16 Q. Let me ask you this, Doctor, were you telling the jury
17 yesterday that this was not a primary lung cancer and instead
18 was a primary renal cancer?

19 A. Yes, I was.

20 Q. Isn't some of this information as a cancer doctor important
21 for you to know from a standpoint of what is the incidence of
22 cancers in the human body when trying to determine whether or
23 not it is a primary lung or a primary kidney?

24 A. One whole piece of -- a whole set of information that we
25 would look at, but I -- as relating to lung cancer, I am not an

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29

MANYAK - Cross

1 expert in that field.

2 Q. With respect to whether or not this is a primary lung
3 cancer, you would defer, for example, to a board-certified
4 pulmonologist, wouldn't you?

5 A. Unless the evidence is so overwhelming as it is in this
6 case that it's a renal cell cancer, which is exactly what it is
7 in my opinion.

8 Q. For you to be able to reach that conclusion, that
9 determination, don't you have to know a little bit about both
10 disease processes?

11 A. Oh, yes, I do.
12 Q. So, do you agree that the majority of lung cancers are
13 caused by cigarette smoking?
14 MR. CESARANO: I object, Your Honor. He is asking
15 specifically about lung cancers, not as they relate to kidneys.
16 THE COURT: Overruled. Answer the question.
17 THE WITNESS: I have not studied the literature in
18 depth about the causes and factors of lung cancer. It is one
19 of those things that are mentioned in the general public that
20 smoking causes lung cancer. What is the actual relationship, I
21 do not know that in any depth.
22 BY MR. COHEN:
23 Q. Well, let's talk about renal cell carcinoma. Do you agree
24 that renal cell carcinoma accounts for ninety to ninety-five
25 percent of malignant neoplasms arising from the kidney?
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MANYAK - Cross

1 MR. REILLY: Same objection, Your Honor. Counsel is
2 reading from a book that has not been identified as an
3 authoritative source by this witness.
4 THE COURT: Overruled. You may answer the question.
5 THE WITNESS: I'm aware that renal cell carcinoma
6 accounts for about ninety percent of kidney cancers.
7 BY MR. COHEN:
8 Q. Did you agree that environmental factors have been
9 investigated as possible causal factors?
10 A. Possible. Emphasize possible, yes.
11 Q. Do you agree that the strongest association with renal cell
12 carcinoma is cigarette smoking, accounting for as many as
13 twenty to thirty percent of cases?
14 A. No, I don't agree with that.
15 Q. Doctor, as a urology specialist who deals with diseases,
16 including cancer of the urological system, are you familiar
17 with the American Cancer Society facts and figures 1999?
18 A. I know that they put out statistics. I don't have those in
19 front of me. Obviously, you are going to bring them to me.
20 Okay.
21 Q. Yes.
22 A. This is one source for cancer statistics, and there are
23 several including some that come from the National Cancer
24 Institute --
25 MR. CESARANO: May I see those?

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MANYAK - Cross

1 THE WITNESS: Yes.
2 BY MR. COHEN:
3 Q. The one that I handed you happens to be 1999, doesn't it?
4 A. Yes.
5 Q. That's the year Bob Allen died, correct?
6 A. Yes.
7 Q. Tell the jury, if you would, looking at those statistics
8 from the American Cancer Society, how many lung cancers, new
9 cases of lung cancers, are estimated, according to that study,
10 in the male population.
11 A. In the male population, according to these numbers here, it
12 states ninety-four thousand.
13 Q. Now tell the jury, if you would, how many reported deaths
14 are estimated as a result of lung cancers, according to that
15 study.
16 A. Ninety thousand, estimated for the year 1999.
17 Q. Now, they also include in that study, don't they, the
18 association of kidney cancer, don't they?
19 A. Well, there is no association with kidney cancer. They

20 mention kidney cancer here.
21 Q. That's what I mean, sir.
22 A. We have to make sure we understand the terminology.
23 Q. Absolutely. They mention kidney cancer, don't they?
24 A. They do.
25 Q. Tell the jury how many reported new cases, according to
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MANYAK - Cross

1 those 1999 statistics, were put out by the American Cancer
2 Society for kidney cancer?
3 A. For kidney and renal pelvis, which includes transitional
4 cell cancers, is thirty thousand.
5 Q. In the male population?
6 A. In the male population is seventeen thousand eight hundred
7 in this compilation.
8 Q. So it's seventeen thousand kidney cancers in the male
9 population compared to ninety thousand in lung?
10 A. Yes.
11 Q. How many deaths are there associated with kidney cancers in
12 the male population?
13 A. Seventy-two hundred, less than fifty percent. Less than
14 fifty percent.
15 Q. Of the reported new cases?
16 A. Well, yes, but that's a misleading statistic. These are
17 new cancers diagnosed versus people that die of the disease in
18 that year. So they're not one of the same. It doesn't mean
19 that less than half the people die of -- that seventeen
20 thousand have died of cancer that year. That's how many people
21 died that year of kidney cancer.
22 Q. Can we at least agree that there are seven to eight more
23 cases of lung cancer, new cases of lung cancer, then kidney
24 cancers in the United States?
25 A. Yes.

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MANYAK - Cross

1 Q. Can we also agree that the death rate associated with lung
2 cancer is ten times greater than the death associated with
3 kidney cancer?
4 A. Sure.
5 Q. Doctor, one of the things that you had told us you did, or
6 some of the work that you have done, was you did some research
7 and you looked at some studies, correct?
8 A. Yes.
9 Q. In that event -- and I should say what you did is you found
10 some articles, some medical literature, some medical research
11 and you relied on them, correct?
12 A. Well, I used them to get an understanding of the issues
13 that we are talking about in this case, yes.
14 Q. You relied on them?
15 A. To some extent, yes. But it wasn't the only source from
16 reliance.
17 Q. I mean, you gave us a list of the medical research you did
18 and you called it your reliance list.
19 A. Well, that's a legal term that you use. I would say it's
20 one of the pieces of information I would look at to look at the
21 facts in this case.
22 Q. By the way, when you do that kind of research, do you
23 charge your time for that?
24 A. Sometimes, yes.
25 Q. In this case, you're compensated for --

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MANYAK - Cross

1 A. I probably did for this. It took a little time to do this,

2 yes.
3 Q. In this case, you are compensated for your time, correct?
4 A. Yes.
5 Q. Tell the jury how much you charge an hour for your work,
6 what your initial retainer is, and how much you charge for
7 coming here today and testifying.
8 A. Sure. The initial review of the case is \$1,250. I charge
9 \$350 an hour for subsequent work, and \$3,000 per half day of
10 court time.
11 Q. So yesterday you were here, let's say, a half a day?
12 A. Yes.
13 Q. And assume you are going to be here another half a day?
14 A. I hope so.
15 Q. Because that will be \$6,000.
16 A. Well, I actually lose money coming here from my practice.
17 I get compensated for the time that I'm away.
18 Q. How many total hours have you put in on this case?
19 A. Somewhere around forty to fifty hours, I would guess.
20 Q. Is that at \$500 an hour?
21 A. It comes to \$350.
22 Q. I'm sorry. So how much have you totally earned and charged
23 the lawyers who called you for your work in this case?
24 A. I haven't submitted the bills. I haven't accepted a
25 preliminary payment. That's unclear. I am not sure. You can

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MANYAK - Cross

1 estimate at forty, fifty hours times \$350. You can do the
2 math.
3 Q. So that's about twelve to fifteen thousand right there?
4 A. Probably, yes.
5 Q. And then six more thousand for the two days?
6 A. Yes.
7 Q. So \$20,000 to testify about your opinions?
8 A. Well, it's an important case to testify in. You know, with
9 these lawsuits that are brought for the wrong reasons --
10 MR. COHEN: Judge --
11 THE COURT: Pardon me, Doctor, we have been here four
12 weeks. We don't want to have to do it all over again and have
13 you come back.
14 THE WITNESS: I am sorry. I apologize if that was out
15 of line. It was not intended to be.
16 THE COURT: The jury will disregard all that. The
17 jury will decide the merits of the case after considering all
18 the testimony of all the witnesses. The question dealt with
19 the compensation, and it's asked of every witness. They are
20 not picking on you. Both sides, everybody asks the same
21 questions.
22 All right. I think he has answered the question.
23 BY MR. COHEN:
24 Q. Doctor, you talked about the difference between renal cell
25 carcinoma and transitional cell carcinoma, correct?

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MANYAK - Cross

1 A. Yes, some of the differences, yes.
2 Q. The majority of cancers, as we just saw, but even in your
3 own opinion, are renal cell carcinomas?
4 A. Cancers of the kidney?
5 Q. Yes, sir.
6 A. Yes.
7 Q. Those are called sometimes RCC?
8 A. That's an abbreviation for renal cell carcinoma, yes.
9 Q. The majority of renal cell carcinomas, RCC, are clear cell
10 type?

11 A. Yes, eighty to eighty-five percent.
12 Q. Not papillary, but clear cell?
13 A. Clear cell carcinoma, yes.
14 Q. The other two are the other --
15 A. Those are other cell types, yes.
16 Q. -- other cell types of RCC?
17 A. Well, there are other patterns too. It's just kind of a
18 way that they look at the entire pathological picture and
19 determine it's one type versus another.
20 Q. The majority of RCCs, almost seventy-five percent, are of
21 the clear cell type?
22 A. Yes.
23 Q. So, in the course of your practice, RCC is commonly
24 referred to as clear cell renal --
25 A. No, actually, we want to know the actual designation
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MANYAK - Cross

1 because there are differences with papillary versus clear cell.
2 A papillary, for example, has a much higher familial
3 occurrence. We don't assume it's anything. We like to have a
4 pathological diagnosis.
5 Q. But in the common use amongst kidney cancer specialists,
6 RCC is commonly referred to as clear cell renal cell carcinoma?
7 A. No, we are actually very specific about the type. That's
8 precisely my point. We do want to know the cell type. If you
9 were to hazard a guess when somebody tells you they have renal
10 cell carcinoma, then you would guess right three-fourths of the
11 time that it would be clear cell carcinoma. Renal cell
12 carcinoma means all of the renal cell carcinoma.
13 Q. Which include those three types, the majority being clear
14 cell?
15 A. Right.
16 Q. One of the articles that you directed us to, that you
17 relied on, to whatever degree you did, was an article called
18 The International Renal Cell Cancer Study on Tobacco Use. Do
19 you remember that one?
20 A. I would have to see it again.
21 Q. Yes, sir.
22 A. Yes, this is one of the articles that we looked at.
23 Q. This was one of the articles that not only did you tell us
24 about during your deposition, but you even provided us a copy
25 of, correct?

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MANYAK - Cross

1 A. I believe so, yes.
2 Q. This was a study done by Doctor McLaughlin, right?
3 A. I, again, would have to see this to agree with -- we will
4 assume that that is the author.
5 Q. Okay.
6 A. I mean, I would like to see it. If you want me to answer
7 specific questions, I do want to see what you are referring to.
8 Q. All right, well, I will tell you what I will do.
9 MR. COHEN: Judge, may I approach?
10 THE COURT: Yes.
11 BY MR. COHEN:
12 Q. If you don't mind, we will read it together so there's no
13 misunderstanding. This is the study of the -- the
14 International Renal Cell Cancer Study on tobacco use that you
15 referenced us to and you relied on, correct?
16 A. Yes, that's one of the articles that I supplied.
17 Q. McLaughlin was one of the principal authors?
18 A. Yes.
19 Q. The very first paragraph that is stated in this study is

20 that, "Cigarette smoking has been found in numerous
21 epidemiological studies to increase the risk of renal cell
22 cancer," correct?
23 A. That's what it says here, yes.
24 Q. "A number of case control studies have found dose response
25 relationships among men?"

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MANYAK - Cross

1 A. That's what the next sentence says, yes.
2 Q. Do you agree with that?
3 A. I think there are other pieces of information here, several
4 other studies where this is unclear. I think that the thing
5 that's consistent with all these studies is we are really not
6 sure what this relationship is. This happens to be one study.
7 For the sake of balance, we -- or I -- want you people to see
8 what we looked at and to see that it is inconsistent.
9 Q. This study goes on to say that, "Cohort studies of smokers
10 have also reported a link with renal cancer," meaning other
11 studies, correct?
12 A. That's what he states here, yes.
13 Q. Do you agree with that?
14 A. Yeah, sure. There are some that are shown, there are
15 others that have not.
16 Q. In this report that you supplied us with it says that, "The
17 purpose of this report is to examine in detail the relationship
18 between tobacco use and the risk of renal cell carcinoma using
19 case control data pulled from the centers around the world?"
20 A. "From six centers around the world."
21 Q. "Six centers around the world," correct?
22 A. That's what it says, yes.
23 Q. Let's look at the -- a conclusion, if you will. All right?
24 "The results of this pooled analysis, the largest
25 study to date" -- and this was published in 1995, correct,

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MANYAK - Cross

1 Doctor?
2 A. Yes.
3 Q. "The largest study to date, by far, provide convincing
4 evidence that cigarette smoking is a causal, meaning the
5 causes, as a risk factor for RCC, accounting for approximately
6 one out of four cases among men," correct?
7 A. And one out of ten among women. That's what it says here,
8 yes.
9 Q. Do you agree with that?
10 A. As I said, if you take all the information that's out
11 there -- and this is one person's opinion, and the other
12 studies out there are inconclusive as well. I am not sure how
13 much relationship there is.
14 There appears to be a slight increased risk, which is
15 different than cause, from patients that smoke to develop renal
16 cell carcinoma.
17 Q. They concluded in the study that you referred us to, that:
18 "In summary, this large-scale population-based pooled analysis
19 of tobacco use and RCC risk confirms cigarette smoking as a
20 causal agent," right?
21 A. That's what it says here, yes.
22 Q. "Indicating that elimination of this habit would contribute
23 to a reduction in the number of renal cell carcinoma cases
24 around the world." That's what it concludes?
25 A. That's what he says. That's his conclusion.

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MANYAK - Cross

1 Q. Do you agree?

2 A. I am not sure about that. As I said, the data from the
3 other studies are very inconclusive to me. I am really not
4 sure, to be honest with you.
5 Q. You are not sure?
6 A. I'm really not sure.
7 Q. You're not sure as to whether or not cigarette smoking is a
8 causal factor --
9 A. That's not what I said. What I said was I am not sure that
10 if you decrease smoking, it will decrease the amount of renal
11 cell carcinoma. What appears to be the case, is if there is a
12 mild association with an increased risk in patients that smoke
13 to develop renal cell carcinoma. I think that's a fair
14 statement. It's a mild increase. It's at least equal to other
15 factors that are also risk factors for development of renal
16 cell carcinoma as -- I am sorry. Go ahead.
17 Q. I'm sorry.

18 THE COURT: Gentlemen, just a moment now while both of
19 you pause, please let each other finish your questions and
20 answers because the court reporter needs to get it down.

21 THE WITNESS: Sure.

22 BY MR. COHEN:

23 Q. Let's look at a couple of the other studies that you
24 referred us to in your reliance list.

25 One is called Obesity, Hypertension, and the Risk of
SYLVIA ALLEN vs RJ REYNOLDS/P.MORRIS - 2/25/03
MANYAK - Cross

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1 Kidney Cancer in Men, correct? You referred that article to
2 us?
3 A. Yes.
4 Q. And you did that, you referred that to us, because that was
5 something you relied on, and you talked about with the jury as
6 far as being a risk factor as you believed in developing renal
7 cell carcinoma, correct?
8 A. Yes, this is one of several studies that were reviewed for
9 this subject.
10 Q. Now, one of the first paragraphs, or I should say on the
11 first page of this particular study, the authors say, "Obesity
12 increases the risk of renal cell cancer, although this
13 association has not been consistently observed in men,"
14 correct?
15 A. That's what it says.
16 Q. In fact, you are familiar that a lot of the studies
17 concerning the association of risk factors or causes for renal
18 cell carcinoma differ greatly amongst gender, meaning whether
19 it's male or female, correct?
20 A. Yes, it's suggested in some studies. It's not consistent
21 in all studies, but it has been suggested in some studies,
22 correct.
23 Q. They also talked about hypertension. They said,
24 "Hypertension is a risk factor, but quantitative data according
25 to levels of blood pressures are limited," correct?

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MANYAK - Cross

1 A. That's what it says, yes.
2 Q. In this very article about obesity and hypertension and
3 kidney cancer, what do they then say?
4 A. The next sentence you have highlighted here says,
5 "Cigarette smoking increases the risk of both types of kidney
6 cancer, and the increase is greater for renal pelvis cancer
7 than for renal cell cancer."
8 Q. And you certainly agree with that?
9 A. I agree with that, yes.
10 Q. Let me jump ahead to another article that you referred us

11 to -- and by the way, with respect to obesity being a risk
12 factor, are you familiar with the fact that the risk factor of
13 that, of being obese, has to do with the longevity of the
14 obesity, correct?

15 A. I am not sure that has ever been pointed out to a great
16 satisfaction.

17 Most of the things that I have read don't mention
18 duration of obesity.

19 Q. Let me show you another study, okay? Risk Factors in Renal
20 Cell Carcinoma, Methodology, Demographics, Tobacco, Beverage
21 Use and Obesity. Do you see that?

22 A. Yes. This is an article I have not reviewed. This must
23 have come from -- it's dated 1988, so it's a little older.

24 Q. Let's see what they say, these authors, conclude about
25 their study concerning --

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MANYAK - Cross

1 A. I am a little uncomfortable just taking things out of
2 context, of this study, not having read the whole study. I
3 will just say that up front.

4 Q. Fair enough.

5 MR. REILLY: Objection, Your Honor. This hasn't been
6 established as an authoritative source.

7 THE COURT: He says he is not familiar with it.

8 MR. COHEN: If I can relate him, Judge, to where in
9 this study? What the study relates to is the McLaughlin study
10 that he relied on.

11 THE COURT: Let's ask him first before you read the
12 article to the jury. Let's find out whether or not he is
13 familiar with it, for starters.

14 Doctor, did you list this as one of the documents that
15 you relied on?

16 THE WITNESS: No, I did not, Your Honor.

17 THE COURT: Are you familiar with this article at all?

18 THE WITNESS: No, I am not.

19 THE COURT: I am going to sustain the objection.

20 Let's move on.

21 BY MR. COHEN:

22 Q. Let me ask you this, Doctor. Do you agree that for
23 overweight, that is for obesity, to increase the risk of renal
24 cell carcinoma, it must be present in young adult life and
25 maintained throughout the older years?

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MANYAK - Cross

1 A. I don't know that. I have never run across that in my
2 review of any literature.

3 Q. Let's look at, again, one of the articles that you did rely
4 on. The Epidemiology of Renal Cell Carcinoma.

5 A. Yes, I am familiar with this one.

6 Q. In this study that you referred us to, it says, "The
7 results of this study was compared with those who never smoked.
8 The odds ratio" -- and tell the jury, what is an odds ratio?

9 A. An odds ratio is an assessment of what the odds are for
10 somebody to develop something over the general population.

11 Q. So the odds ratio for renal cell carcinoma among current
12 cigarette smokers was 1.4, which means almost one and a half
13 times the greater risk, correct?

14 A. That means -- yes. I will accept that.

15 Q. And that's for men, right?

16 A. Yes.

17 Q. And then there was a trend with respect to this study, that
18 is, that risk, that odds ratio risk, increased with the pack
19 years of smoking, correct?

20 A. Yes, in men.
21 Q. That's right.
22 And as you increase the amount of smoking as you
23 increase the years of smoking, there is even a far greater risk
24 of contracting kidney cancer as a result of that dose
25 relationship, right?

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MANYAK - Cross

1 A. No. What it says is consistent in several studies. I
2 think that is a trend. If there is a longer smoking history,
3 that there is a higher risk relative to developing kidney
4 cancer. That doesn't mean it causes it. That means that your
5 risk increases somewhat. It increases slightly, actually, if
6 you look at all of the different studies that were provided.
7 That's why it's important to read several of these
8 studies at the same time so that you can get the picture as to
9 what is consistent and what is not consistent.
10 Q. So far, can we at least agree that every one of the studies
11 that you referred us to makes the link between cigarette
12 smoking being an associated risk, being a relative risk, and
13 having a causal link as a risk factor to kidney cancer?
14 A. It has a mild risk association with the development of
15 kidney cancer.

16 The thing that disturbs me about these kind of studies
17 is it is extremely low for women. You would think that if it's
18 a carcinogenic problem that causes kidney cancer, it would be
19 the same amount in women. I am really unclear what these
20 numbers mean. With a slight increase like that, I am not sure
21 what it means. It's reported and it's there, so we talk about
22 it.

23 In my own mind, I am really unconvinced that that's a
24 cause for kidney cancer development because I would expect to
25 see that in women as well.

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MANYAK - Cross

1 Q. Don't you recognize that some of those studies and some of
2 those authors who recognize the distinction between men and
3 woman, a large part of it is hormonal?

4 A. A large part of what is hormonal?

5 Q. The distinction, the difference, as to why whose risk
6 factors are sometimes greater in women as opposed to men, or
7 vice versa with respect to --

8 THE COURT: Wait a minute. Gentlemen. Repeat your
9 question and finish it, and then we will let him start his
10 answer.

11 BY MR. COHEN:

12 Q. I thought what you were indicating, Doctor, was that you
13 are surprised that there's a difference in the relative risk of
14 some agents for causing cancer between men and women?

15 A. I am referring to specifically kidney cancer.

16 Q. That's what I mean. You were surprised that there was a
17 difference between men and women and their relative risks for
18 developing kidney cancer from certain known causes?

19 A. Yes, I am surprised. I would think that a cause for cancer
20 would be indistinct or it should be the same for men and women
21 if it's really a cause for cancer.

22 Q. As far as some of the risk factors that you discussed with
23 the jury yesterday, the one thing you talked about was also
24 genetics. Do you remember that?

25 A. Yes.

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MANYAK - Cross

1 Q. You don't have any information about Bob Allen's family

2 history, do you?
3 A. We have a small amount of information, yes.
4 Q. Do you know about whether or not his mom, his dad developed
5 kidney cancer?
6 A. I don't believe they did.
7 Q. Do you know how old they were when they died?
8 A. I don't recall that.
9 Q. Do you recall looking at any history of any medical charts
10 and records that they were in their mid to late 80s when they
11 died?
12 A. I do not recall that.
13 Q. In any event, you do not know, and you have no information
14 if Bob Allen's kidney cancer that you think was a primary
15 kidney cancer was as a result of genetics, do you?
16 A. I think we established that yesterday that it was
17 speculative and the jury was instructed on that matter. So
18 that's absolutely correct. We don't know anything about that
19 further.
20 Q. Doctor, you talked a little bit about some of the role of a
21 urologist like yourself in dealing with diseases and kidney
22 cancers, and you talked a little bit about pathology. Do you
23 remember that?
24 A. Yes.
25 Q. You said you reviewed the pathology of -- at least the
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MANYAK - Redirect

1 pathology reports on Bob Allen, correct?
2 A. I reviewed the reports. I did not review the actual slides
3 themselves.
4 Q. But you are familiar, are you not, Doctor Manyak, that
5 certain immunohistochemical staining can be done on biopsied
6 tissue which can give some very clear and precise information
7 as to cancer, correct?
8 A. I think stains -- first of all, this is out of my area of
9 expertise. I can't elaborate on various stains. I would defer
10 to the pathologist to determine which stains might be useful to
11 gather the information for the biopsy specimen.
12 Q. Fair enough. Let me just ask you this question as it
13 relates to your practice. You have never seen a kidney cancer
14 test positive for mucicarmine, have you?
15 A. Not that I recall.
16 MR. COHEN: Judge, if I could just have one moment.
17 THE COURT: Yes, sir.
18 MR. COHEN: Thank you, Judge. Those are my questions.
19 THE COURT: Mr. Cesarano.
20 MR. CESARANO: Thank you, Your Honor. If I could have
21 a second to organize.

REDIRECT EXAMINATION

23 BY MR. CESARANO:

24 Q. Doctor Manyak, you were asked a number of questions about
25 the therapy and the treatment that was given to Mr. Allen in
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MANYAK - Redirect

1 the hospital, and you were referred to this record with respect
2 to the interleukin and the stopping and starting of the
3 interleukin.
4 I would like to draw your attention to item number 2
5 up there. What is that? What does that say and what is the
6 significance, please?
7 A. It is an abbreviation for diagnosis. It says, "Renal cell
8 carcinoma, slash, continuous infusion pretty common at
9 interleukin-2, or IL-2." What that is is a standard notation
10 when a patient is admitted or therapy starts, and not

11 infrequent to the diagnosis is placed there. That's what the
12 significance of that is.
13 Q. Now, Doctor Manyak, you were also shown this document.
14 Looking at the highlighted part, down to the next-to-last line,
15 we see, "Patient wants something, Rx." What is that last word
16 there?
17 A. It looks to me like it might be thalidomide.
18 Q. Is thalidomide a medication that you are familiar with in
19 your practice?
20 A. I don't use it in my practice, but I am familiar with it.
21 I think we all heard about thalidomide from thirty or forty
22 years ago. It is now being looked at as a very potent
23 medication for use against cancer because it blocks the growth
24 of very small vessels that are necessary to nourish cancer.
25 That's called anti-angiogenesis. Thalidomide is an

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MANYAK - Redirect

1 anti-angiogenic compound. It is being looked at for a variety
2 of cancers.
3 Q. Does that include renal cell cancer as well?
4 A. Yes, I believe it is.
5 Q. This again is the discharge summary, the second page of the
6 discharge summary. There is a highlighted portion up there.
7 We don't need to read it to the jury because they can read it
8 themselves. If you could read it to yourself and tell me what
9 the significance of that is. I see there is a "secondary
10 effect of the thalidomide" and so forth.
11 A. Yes. That essentially states that the family elected, in
12 the face of this very serious condition, to continue with
13 therapy. And that the thalidomide was started, and that the
14 side effect associated with thalidomide, which is sleepiness,
15 somnolence, he was being treated for that with Ritalin to try
16 to offset that.
17 Q. We have a course of interleukin that was started and
18 stopped because of side effects, then we have another drug
19 that's being tested or tried for kidney cancer as well.
20 Does that support your opinion in this case that
21 Mr. Allen was suffering from renal cell cancer?
22 A. Yes.

23 MR. CESARANO: May I approach the witness, Your Honor?

24 THE COURT: Yes, sir.

25 BY MR. CESARANO:

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MANYAK - Redirect

1 Q. Doctor Manyak, I believe you were asked about this article
2 in the National Renal Cell Cancer Study?
3 A. Yes.
4 Q. I would like to direct your attention to page 197 of that
5 article where it states, "The magnitude of the association
6 between cigarette smoking and RCC is moderate and would be
7 difficult to detect in a small study or in one using hospital
8 controls where the prevalence of smoking is likely to be higher
9 than in the general population."
10 Could you explain to us what that means, please?
11 A. I think it's self-explanatory from the standpoint of the
12 association of renal cell carcinoma and cigarette smoking to be
13 moderate. What he is pointing out here in his comment is that
14 when you look at a study, you can't take a small study and
15 extrapolate and say this is what happens over thousands of
16 people because the statistics are not strong enough to support
17 that.
18 One of the very important things that we look at
19 whenever we look at a study to review it before it's published

20 is how strong is this statistical conclusion. Then you can
21 draw from there. What he's saying is that several of these
22 studies are small and don't support a strong association with
23 kidney cancer in smoking.

24 Q. I want to ask you also about this article. You were asked
25 about this one, Epidemiology of Renal Cell Carcinoma?

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MANYAK - Redirect

1 A. Yes.

2 Q. Over here there is a section on body weight.

3 A. Okay.

4 Q. It states, "At least five case controlled studies, four
5 from North America and one from China, reported a significantly
6 elevated risk of renal cell cancer in association with body
7 weight with an OR" -- is that the odds ratio?

8 A. Yes.

9 Q. -- "with an OR of 2.7 and 2.5 in men in the highest body
10 mass index level, and OR from 2.2 to 3.6 for either sex, with
11 significant trends in risk. An American study found a forty
12 percent increase in risk which was significant only in men."

13 Do you agree with that statement or is that what your
14 research has shown or turned up?

15 A. I think, again, this points out to the fact that there is
16 an association in several studies with obesity or overweight
17 and renal cell carcinoma development. Again, this literature
18 is erratic in some respects. This is a discussion of five
19 different case control studies, which is the right kind of
20 study you have to do to determine whether a factor is
21 affecting, in this case, cancer. Case control studies are
22 appropriate to have the right thing to measure it against to
23 see if it's effective. That's, I think, fairly strong evidence
24 to suggest that their conclusion is solid.

25 Q. So in talking about risk factors now, and that's what these

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MANYAK - Redirect

1 two studies addressed, and that's what you were asked about on
2 cross-examination by Mr. Cohen, how does -- according to the
3 literature and the research that you're familiar -- let me back
4 up a minute.

5 Let me ask you, first of all, you looked at a number
6 of different studies and articles on research; did you not?

7 A. Yes.

8 Q. Why do you look at a number of them? Why do you look at
9 several?

10 A. Well, I think you want to get as much of a balanced
11 approach to an issue as you can. Unless there is something
12 that is strikingly definite about one paper or one report, it
13 is common practice for us to get as many reports as we can to
14 look at the issue. Not only just for this, but for everything
15 we do in medicine.

16 Q. When you get as many reports as you can, those reports or
17 those studies will cover the entire range of findings, will
18 they not?

19 A. Hopefully, that's the plan.

20 Q. That's the reason why you look at so many, so that you can
21 see the entire range of research, results and findings,
22 correct?

23 A. Yes, because some studies may have flaws. If you rely on
24 just one, then you may come to the wrong conclusion.

25 Q. You do that so that you are able to come in and present the

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MANYAK - Redirect

1 entire picture, correct?

2 A. Yes.
3 Q. Talking about risk factors, in the course of the research
4 and the studying that you have done, how does cigarette smoking
5 compare as a risk factor to the other risk factors that
6 Mr. Allen had which include hypertension, obesity, being a
7 male, being in the age group of fifty to seventy?

8 A. And diabetes.

9 Q. And diabetes.

10 A. Looking at the risk factors of diabetes, hypertension and
11 obesity and comparing them to the cigarette smoking issue, they
12 are at least equal to each other. In several cases obesity and
13 hypertension and diabetes are a little higher. I think that's
14 probably not statistically significant. It would be a very
15 fair statement to say that they are about equal as far as their
16 relative risk association.

17 Regarding males and being a male and being in the age
18 range, there is a fairly high association with that. We know
19 that kidney cancer occurs twice as often in men as in women.
20 That certainly would increase his risk. He was in the right
21 age range for the peak incidence of kidney cancer.

22 Q. When you say kidney cancer occurs twice as often in men as
23 in women, does that mean that odds ratio or the relative risk,
24 I'm sorry, is two?

25 A. No, you know, I am not sure I can answer that

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MANYAK - Redirect

1 appropriately. Not being a statistician, I am not comfortable
2 trying to estimate that.

3 Q. Okay. In someone such as Bob Allen who has all of these
4 various risk factors, including age gender and the other ones
5 we have talked about, is there any way that you can conclude or
6 anyone can conclude what caused his renal cell carcinoma?

7 A. No, I don't think you can.

8 Q. You were asked about some statistics from the American
9 Cancer Society?

10 A. Yes.

11 Q. Do statistics tell us what type of cancer Bob Allen had?

12 A. No.

13 Q. You told us on cross-examination that his course of
14 treatment was just one piece of the evidence that led you to
15 your conclusion. What are the other pieces of evidence that
16 you considered other than his course of treatment, other than
17 the medication that was administered and other than the
18 pathology? You used all of those three, correct?

19 A. Yes.

20 Q. What else did you --

21 A. I think the first important piece is the pathological
22 diagnosis that was rendered by two different pathologists
23 stating this is consistent with renal cell carcinoma.

24 Secondly, the clinical course that occurred with the
25 development of a renal mass that progressed in size and that

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MANYAK - Redirect

1 other lesions showed up in other places is important and
2 strongly suggests renal cell carcinoma.

3 The fact that the occurrence of the discovery of the
4 metastatic deposit in his foot that was biopsied is very
5 consistent with renal cell carcinoma. In fact, that is the
6 most common type of cancer that occurs when you find a
7 metastasis in the foot.

8 The clinical course clearly supported that. Very
9 strong evidence is seen on the records that we looked at and
10 went through in detail yesterday with the CT scan demonstrating

11 at the time of diagnosis, clearly a renal mass that was solid
12 and would be, in my opinion, very, very highly suspicious for
13 kidney cancer at the time of his original diagnosis. Putting
14 all of that together is very strong evidence. That's why I say
15 whether or not the interleukin had any relative play or not is
16 a relatively lesser piece of information.

17 It's somewhat supportive. But the strong facts are
18 the appearance of the x-rays, the pathological diagnosis and
19 the clinical course of this patient's problem. That is, it's
20 renal cell carcinoma. That's what it is.

21 Q. You were also asked some questions about renal cell
22 carcinoma and the differences between renal cell and
23 transitional cell carcinoma?

24 A. Yes.

25 Q. Transitional cell carcinoma, and you explained a little bit
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MANYAK - Redirect

1 to the jury yesterday what the cross-section of the kidney,
2 where it arises in the collection area?

3 A. Yes.

4 Q. You also were asked about cancers of the renal pelvis and
5 ureter. Is that renal cell carcinoma, cancers of the renal,
6 pelvis and ureter; is that the same thing?

7 A. No, no, no. That transitional cell carcinoma.

8 Transitional cells line the collecting system, which is that
9 area where it all collects before it goes down the ureter,
10 renal is the tube that goes to the bladder. That area is
11 called the renal pelvis. It's where the collecting system
12 comes together and forms a little pool and then goes down the
13 ureter. That's all transitional cell carcinoma.

14 Q. If it were a transitional cell, you would expect to see a
15 tumor in that area?

16 A. Yes.

17 Q. Whereas, in our case we saw it on what's called the cortex?

18 A. Yes, it was on the periphery, which is completely
19 different. You may see a transitional cell in the internal
20 portion of the kidney that looks like it's coming from the
21 solid tissue. When it has arisen from that internal renal
22 pelvis area, it wouldn't appear like that. It wouldn't appear
23 like what we saw there, which is clearly an external peripheral
24 lesion that is just starting to contour of the kidney.

25 Q. The association between smoking and cancers of the renal
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MANYAK - Redirect

1 pelvis and ureter, or transitional cell, is higher than the
2 association between smoking and renal cell carcinoma, correct?

3 A. It's very significantly higher, yes.

4 Q. Let me show you an article entitled Cigarette Smoking and
5 Cancers of the Renal Pelvis and Ureter.

6 MR. COHEN: Point of clarification, is that one of
7 articles we went over?

8 MR. CESARANO: You did not address this article on
9 cross.

10 MR. COHEN: Then I object. One, it's redirect and
11 it's bolstering.

12 THE COURT: Has this article been shown to or
13 furnished to the plaintiffs?

14 MR. CESARANO: This article was shown to Doctor
15 Feingold by the plaintiffs.

16 THE COURT: Was shown to --

17 MR. CESARANO: Doctor Feingold in their direct
18 examination.

19 THE COURT: I see. So the plaintiffs have reviewed.

20 Do you understand what the article is? We didn't get the
21 author, but show him a copy of it. All right. The objection
22 is overruled. You may ask him about it.

23 MR. CESARANO: That has been marked as Defendant's
24 Exhibit PM481.

25 THE COURT: Thank you.

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MANYAK - Redirect

1 BY MR. CESARANO:

2 Q. Let's go straight to the conclusion or the abstract of this
3 article. Could you explain what this article indicates with
4 respect to the association between cigarette smoking and
5 transitional cell carcinoma?

6 A. Yes. The title is Cigarette Smoking and Cancers of the
7 Renal Pelvis and Ureter. It is by McLaughlin, again, who is an
8 author on some of these other papers that we have discussed,
9 and some people from the National Cancer Institute that I know.

10 The conclusion says, "The attributable risk estimates
11 indicate that approximately seven of ten cancers of the renal
12 pelvis and ureter among men --"

13 THE COURT: A little bit slower.

14 THE WITNESS: I apologize. I'm sorry.

15 THE COURT: A little bit slower. When you are reading
16 it goes fast.

17 THE WITNESS: You are right. I apologize.

18 THE COURT: Could you back up just a little?

19 THE WITNESS: Sure. I will start over with the
20 conclusion. It says, "Attributable risk estimates indicate
21 that approximately seven of ten cancers of the renal pelvis and
22 ureter among men and almost four of ten among women are caused
23 by smoking."

24 "The results of this study, the largest to date,
25 confirm that cigarette smoking is the major cause of cancers of

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MANYAK - Redirect

1 the renal pelvis and ureter, and the cessation of smoking could
2 eliminate a large portion of these tumors."

3 BY MR. CESARANO:

4 Q. Just to make clear, Mr. Allen did not have cancer of the
5 renal pelvis and ureter, did he?

6 A. He did not.

7 Q. You were also asked a series of questions of cancer
8 metastasizing and spreading, I believe from the lung to the
9 kidney. If, in fact, Mr. Allen's cancer had been a lung
10 primary and had spread to the kidney, what would you have
11 expected to see in the radiographs and the records and so forth
12 that you reviewed?

13 MR. COHEN: Objection, Your Honor. This is
14 repetitious. It was gone over on direct.

15 THE COURT: Well, a certain amount of going back over
16 some of the direct is permitted, but I think that we have gone
17 pretty much in depth. I will let you go a little further. If
18 it is in the record, it is, of course, arguable to the jury.
19 He doesn't have to repeat it. A certain amount of that is
20 permitted. Go ahead.

21 MR. CESARANO: Thank you.

22 THE WITNESS: I think we covered, as you say,
23 yesterday in showing the photos of what the classical
24 appearance of lung cancer going to the kidneys is. That is,
25 that it happens on both kidneys, and it happens on multiple

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MANYAK - Redirect

1 locations. That's what we would expect. Over the course of

2 time we see only still the one lesion in the kidney. That, to
3 me, very strongly supports that this was primary kidney cancer
4 and not metastatic lung cancer. We would expect other deposits
5 to show up.
6 BY MR. CESARANO:
7 Q. Mr. Cohen asked you also about whether or not lung cancer
8 could spread to the bone. What is the most common type of
9 cancers to spread to the bone? Is lung cancer the most common
10 type that will spread to the bone?
11 A. It is not the most common, no. It is one that does go to
12 the bone, but it's not the most common.
13 Q. What in your opinion is the most common?
14 A. Prostate cancer is the most common. There are essentially
15 five tumors that go to bone. Prostate, kidney, thyroid, lung
16 and breast cancers all are known to go to the bone. Prostate
17 being the most common. Kidney being the second or third most
18 common ahead of lung cancer going to the bone. Occasionally,
19 colon cancer can go to the bone too. It happens about ten
20 percent of the time.
21 Q. Is kidney cancer more likely to spread to bone than lung
22 cancer?
23 A. Yes, on a statistical basis, yes.
24 MR. CESARANO: Thank you. May I have just one moment,
25 Your Honor?

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KAPLAN - Direct

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1 THE COURT: Sure.
2 MR. CESARANO: Thank you. That's all I have.
3 THE COURT: Thank you, Doctor Manyak. You may step
4 down.
5 THE WITNESS: Thank you, Your Honor.
6 THE COURT: Ladies and gentlemen, it's 10:35. We have
7 been in session for one hour and a half. We will take a
8 fifteen-minute recess and resume at ten minutes to eleven. You
9 folks step into the jury room, please.
10 [The jury leaves the courtroom.]
11 [There was a short recess.]
12 THE COURT: Bring in the jury, please.
13 [The jury returns to the courtroom.]
14 THE COURT: Thank you. Be seated.
15 Your next witness, please.
16 MR. REILLY: Thank you, Your Honor. Our next witness
17 is Doctor Eric Kaplan.
18 COURTROOM DEPUTY: State your name, please, spelling
19 your last name for the record.
20 THE WITNESS: Eric Michael Kaplan, K-a-p-l-a-n.
21 ERIC MICHAEL KAPLAN, DEFENDANT'S WITNESS, SWORN.
22 DIRECT EXAMINATION
23 BY MR. REILLY:
24 Q. Doctor, would you please tell the jury your name?
25 A. Eric Kaplan, M.D.

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KAPLAN - Direct

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1 Q. Please tell the jury your profession.
2 A. I am a medical doctor and a psychiatrist.
3 Q. Can you tell me where you are licensed to practice
4 medicine?
5 A. I'm licensed in the State of Florida.
6 Q. Tell me where you live.
7 A.
8 [DELETED].
9 Q. How long have you been practicing psychiatry?
10 A. I completed my residency in 1990, so I have been in private

11 practice for approximately thirteen years.
12 Q. Can you tell the jury what the practice of psychiatry is
13 about. What is psychiatry?
14 A. Sure. Psychiatrists are the medical physicians that
15 specialize in diagnosis and treatment of people who suffer from
16 various mental illnesses. In addition, we are responsible for
17 diagnosing and treating people who have problems with substance
18 abuse disorders. We are the specialists who focus on
19 behaviors, and if people want to make some changes in
20 behaviors, we assist them.
21 Q. Can you tell the jury where you went to medical school?
22 A. I went to medical school right here in Miami. That was
23 1982 to 1986.
24 Q. Doctor, during the time that you were in medical school,
25 did you receive any honors?

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KAPLAN - Direct

1 A. I did. I received an award. I think it's the Herman
2 Selinsky award, something like that. Each year at University
3 of Miami they give an award to the student who did best in
4 psychiatry rotation, so my fourth year of med school I won that
5 award.
6 Q. While you were in medical school, did you do work in the
7 area of substance abuse?
8 A. I did.
9 Q. Tell the jury about that.
10 A. As part of every medical student's training, the first two
11 years is pretty much like going to high school in terms of you
12 sit in a class and they teach you a lot about medicine,
13 medications, illnesses, things like that. As part of that
14 education, you learn about psychiatry and mental illness and
15 you learn about substance abuse disorders and you learn about
16 tobacco-related illnesses and treatments and nicotine and
17 pharmacology of nicotine.
18 In the third year you get to meet with patients and
19 you learn how to do physical diagnosis and treat illnesses.
20 During the third year you go through all your different
21 rotations.
22 In medicine, I had the experience of working with
23 patients who had various respiratory and other disorders. You
24 do rotation in psychiatry. In the psychiatry rotation, I had
25 experienced not just book learning, but clinical experience

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KAPLAN - Direct

1 working with patients who had different mental illnesses and
2 substance abuse disorders and some issues regarding nicotine
3 and tobacco use and helping people stop smoking, if they were
4 interested.
5 Finally, in the fourth year you get to pick more of
6 what they call an elective. I was always interested in
7 psychiatry, so I took more psychiatric courses and rotations,
8 and as part of that a lot of the focus was substance abuse
9 disorders, and that included people that were smokers who
10 wanted to stop. That's the different experiences in medical
11 school.
12 Q. Doctor, did you go to more than one medical school? Did
13 you also attend other medical schools aside from University of
14 Miami?
15 A. During the fourth year you get to do what they call
16 externships. I was always a student at the University of
17 Miami. You get to try out other med schools to see, you know,
18 perhaps you would like to do your residency there or they may
19 offer some classes that they didn't have at Jackson Memorial.

20 So I went to University of California, Davis, which is in
21 Sacramento, California. I did I think it was a two to
22 three-month rotation on an inpatient psychiatry unit.
23 They had people with a variety of psychiatric
24 illnesses. Also, they had a substance abuse unit there.
25 Again, I got additional training in how to treat people, how to

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KAPLAN - Direct

1 diagnose, how to help people who had different substance abuse
2 disorders, how to learn to live drug-free, those kind of
3 things.
4 Q. Doctor, I think it's a forgone conclusion you did a
5 residency in psychiatry?
6 A. Yes, I did.
7 Q. Tell us where you did that.
8 A. I decided to stay in Florida and decided to go to
9 University of South Florida in Tampa for their psychiatry
10 department. Let's see, that was 1986 to 1990.
11 Q. Did you receive any awards during your residency?
12 A. I did. I was chief resident my last year. I received an
13 award for the resident who they felt did the best during the
14 residency. I think that was the Hibbs-Bourkard award,
15 something like that. Then I did a paper on psychiatric aspects
16 of AIDS. So I received an award for that also.
17 Q. Doctor, can you tell the jury if you worked on substance
18 abuse issues for care and treatment of patients during your
19 residency?
20 A. Sure. A lot more than med school. That was a focus.
21 Psychiatry residencies are four years. The first year really
22 the focus is internal medicine. You actually are working with
23 the internists training, and you do about three or four months
24 as a neurologist.
25 So the first-year training was a lot of the medical

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KAPLAN - Direct

1 aspects of substance abuse disorders, what can happen if people
2 abuse substances and medical complications and withdrawal
3 issues and how to treat them medically, and then the last three
4 years were focused on actually being a psychiatrist, learning
5 how to really delve into understanding these abuse disorders.
6 And we had training treating people outpatient and treating
7 people on an inpatient unit. It's a lot more extensive
8 training.
9 Q. During your residency, were you involved in substance abuse
10 clinics?
11 A. Yes. In the hospital itself, worked in several hospitals
12 on a rotation. Basically, all you do for six months or a year
13 is treat patients on these inpatient units. There were a wide
14 variety of types of patients, people who had alcoholism and
15 cocaine abuse or dependence, and heroin and other narcotic
16 abuse problems. Some of them were smokers and some of them
17 were interested in stopping, so we had experience in treating
18 people who wanted to stop smoking.
19 In addition, at the V.A. Hospital, which is the James
20 A. Haley Hospital, that's in Tampa, they had a smoking
21 cessation clinic. I think it was approximately six months, but
22 I had experience working in that clinic trying to help people
23 who were interested in stopping smoking.
24 Q. Doctor, after you completed your residency, what did you do
25 after your residency?

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KAPLAN - Direct

1 A. I met my wife during residency and we decided to make a

2 life in Tampa. Stayed in Tampa, Florida, and started an
3 outpatient office. At the same time, I had the good fortune,
4 they were opening up a new psychiatric hospital a little north
5 of Tampa in Pasco County, which is the county north of
6 Hillsboro County, which is Tampa, and they asked me to run
7 their adult inpatient unit.

8 So I had kind of a mixed practice. I treated patients
9 seven days a week in the hospital who had different mental
10 illnesses and substance abuse disorders. I ran their adult
11 inpatient program. Then usually I would see them until about
12 eleven a.m., and then I would go to my outpatient office and I
13 treat people in an outpatient clinic, my office, about five
14 days a week.

15 Q. What kind of substance abuse patients were you dealing
16 with?

17 A. We had a separate alcohol and drug treatment program.
18 Mostly inpatient, but some outpatient. A wide variety.
19 Similar as in med school and residency. People with alcohol
20 abuse problems. Cocaine was quite a problem. Narcotics, like
21 heroin, was a big problem. Some people who have serious abuse
22 in marijuana, although that was not common. Again, as it
23 relates to smoking, some of those people smoked, some didn't.
24 Other people who smoked, if they wanted some assistance in
25 stopping, we certainly tried to help them.

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KAPLAN - Direct

1 Q. Did your responsibilities at Charter change over time?

2 A. They did. About two years after I started there the
3 medical director left. The medical director is the chief
4 doctor in charge of the hospital as it relates to medical
5 issues. They asked me to kind of step up and run the hospital,
6 so I became medical director at Charter Pasco, and I stayed
7 medical director there for --

8 THE COURT: I am slowing you down a minute.

9 THE WITNESS: I'm sorry.

10 THE COURT: Approximately when was that?

11 THE WITNESS: I became medical director approximately
12 1992.

13 THE COURT: Okay. Go ahead.

14 BY MR. REILLY:

15 Q. As slowly as I talk, Doctor, I thought maybe we would even
16 each other out.

17 A. I'm sorry. I have a tendency to talk a little quickly. I
18 stayed medical director until approximately 1997.

19 Q. Can you give the jury a sense of how many substance abuse
20 patients would have been patients at Charter during the time
21 you were involved in that program?

22 A. Sure. I am not going to be exact with the number because
23 there's no way I can recall. Patients running through the
24 program from the whole time I was there, probably in the
25 thousands. Patients who I personally treated them as their own

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KAPLAN - Direct

1 physician, six hundred, seven hundred. Something like that.

2 Q. Those are just substance abuse patients, patients that have
3 alcohol problems or heroin problems or cocaine problems, things
4 of that nature?

5 A. Correct. In addition, I treated patients on the adult unit
6 and the geriatric unit and sometimes the child and adolescent
7 unit. Those people usually suffer from depression who are
8 manic depressive disorder or panic disorder or Alzheimer's
9 disorder for people on the geriatric unit. So it varied.

10 Q. Did you design a smoking cessation program while you were

11 there?
12 A. I was part of a group. Actually, a few years after I
13 started there, I also ran the alcohol and drug program. I was
14 director of that as well as being director of the hospital.
15 Part of what we did there is for people that were smokers who
16 were interested in stopping, we developed additional therapies
17 for them, a smoking cessation track, so to speak.
18 I was part of a committee that put together
19 information, types of treatments, medical-psychological
20 behavioral therapies to help them stop smoking. I also was
21 involved in a similar track at another hospital that I
22 consulted at.
23 Q. I'm going to ask you if you worked at more than just
24 Charter Hospital, but do you have any sense of how many
25 patients would have gone through your smoking cessation program

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KAPLAN - Direct

1 at Charter?
2 A. Again, probably in the thousands. In terms of me actually
3 being their doctor and working with them, that would be in the
4 hundreds.
5 Q. Doctor, did you have responsibilities at other hospitals
6 aside from Charter?
7 A. I did.
8 Q. Tell the jury about that.
9 Sure. It's pretty common for psychiatrists to do
10 consultation liaison work. That's a fancy name. It just means
11 that another medical doctor who's not a psychiatrist wants some
12 guidance in treating psychiatric illness or substance abuse
13 disorders, they ask us for a consultation. I would do consults
14 at several hospitals: University Community Hospital, the
15 teaching hospital which is Tampa General Hospital, and another
16 teaching hospital which was the University Psychiatric Center.
17 Then there was a hospital called Care Unit of South Florida.
18 That is a separate and distinct alcohol and substance abuse
19 hospital.
20 So when they had a person who had a psychiatric issue
21 or they wanted some guidance in helping treat that person, I
22 was their primary psychiatrist who they consulted with.
23 Q. Doctor, did you assist people in quitting smoking at those
24 other hospitals?
25 A. I did. Not that much at Tampa General and University

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KAPLAN - Direct

1 Community. But at Care Unit of South Florida, as I mentioned,
2 part of what they had was a separate track that they added to
3 patients who were alcoholics or other substance abuse disorders
4 who wanted to stop smoking. I was part of a committee that
5 helped design some of these programs that provided
6 psychological therapies, behavioral therapies, when
7 appropriate, some biological medication therapies to help
8 people stop smoking who were smokers.
9 Q. Doctor, do you have any medical teaching responsibilities?
10 A. I do. When I finished my residency in 1990, I joined a
11 clinical faculty at the University of South Florida psychiatry
12 department. Basically, what that means is I am a volunteer. I
13 volunteer teaching medical studies, and I volunteer teaching
14 residents how to perform psychiatric evals, how to treat
15 various disorders.
16 Q. How long have you been doing that?
17 A. Since 1990.
18 Q. Doctor, can you tell this jury if you are board certified?
19 A. I am. The main board for psychiatrists is the American

20 Board of Psychiatry, Neurology. I am board certified by that.
21 A few other boards that I'm a member of, The American Board of
22 Disability Analysts, and the American Board of Forensic
23 Medicine.

24 Q. Doctor, when did you become board certified?

25 A. As soon as they let me. The way it works is you finish
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KAPLAN - Direct

1 your residency. Approximately a year after going to practice,
2 they let you sit for the written boards. You take a test.
3 About fifty percent of psychiatrists pass it. If you pass it,
4 then they let you sit for the oral boards where you actually
5 will meet in front of a group of doctors and patients and they
6 ask you a whole bunch of questions. If you pass that, then you
7 are board certified. I passed both whenever I was allowed to
8 take those tests.

9 Q. Tell the jury, what is psychopharmacology?

10 A. Psychopharmacology is the study of how medications or other
11 substances affects the brain, so it affects the brain in terms
12 of what chemicals these medications can influence and different
13 parts of the brain like receptors that these chemicals can
14 influence.

15 Q. Doctor, have you published in peer-review journals on the
16 subject of psychopharmacology?

17 A. I have. Psychopharmacology is one of my real interests. I
18 have performed different medical studies, and I have published
19 on various issues regarding psychopharmacology.

20 Q. Have you lectured on the topic of psychopharmacology?

21 A. I have and I do. I enjoy lecturing. I lecture mostly to
22 physicians and I teach them in several areas. I like to teach
23 clinicians how to recognize and treat mental illnesses, like
24 depression, both psychotherapy and medications, although my
25 focus is medications. I do a lot of lecturing on

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KAPLAN - Direct

1 anti-depressant medications and other medications in terms of
2 the psychopharmacologies or how these medications actually
3 affect brain chemistry and then how they affect people when
4 they take these medications.

5 I have done some research on withdrawal syndromes,
6 medications that absolutely are not addictive, like
7 anti-depressants, I've done some research on withdrawal. Even
8 though they are not addictive, people can go through withdrawal
9 symptoms. So I've done some research on that also.

10 Q. You are a very fast speaker, Doctor.

11 A. I am sorry about that.

12 Q. I will slow this down just a little bit.

13 Doctor, can you tell the jury whether or not, in
14 lecturing, you have lectured on psychopharmacology both here
15 and abroad?

16 A. I have. I have lectured all over the United States and I
17 have lectured on psychopharmacology in some other countries,
18 France and Scotland.

19 Q. Can you tell the jury if you have lectured on
20 psychopharmacology as it relates to nicotine?

21 A. I have, although that's not a primary focus of my
22 presentations. I have lectured on the topic of biologically,
23 how to treat nicotine dependents. Some anti-depressants have
24 been approved for the treatment of nicotine dependents. You
25 may have heard of a medication called Zyban. Zyban is an

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1 anti-depressant. Wellbutrin is another name for that. As part

2 of my presentations, I have lectured on the many uses of
3 anti-depressants.

4 Anti-depressants are used not just to treat
5 depression. We treat anxiety disorders and obsessive
6 compulsive disorders and some substance abuse disorders. I
7 have given lectures on how anti-depressants can be used in the
8 treatment of nicotine dependence.

9 Q. Can you tell the jury whether or not you are involved in
10 research for drug therapy for nicotine dependence?

11 A. I haven't been, although I just completed a protocol.
12 There is a new medication just released called Strattera. Many
13 of you may not have heard it because it was just released. It
14 is for children and adolescents and adults who have attention
15 deficit disorder, ADD or ADHD.

16 The way it works, which chemicals it works on, it may
17 provide some benefit for people who want to stop smoking. I
18 started a protocol in terms of doing a research study. I am
19 just in the initial stages. A protocol just means the steps
20 you will go through to start a study. What kind of patients
21 and how do I find out they have a diagnosis and how do I know
22 if the med's working or not?

23 I have not gotten any patients yet for this study, but
24 I am going to start it. It is an interest of mine.

25 Q. Doctor, can you tell us if you are a member of any

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1 professional psychiatric organizations?

2 A. I am. I have been a member of the American Psychiatric
3 Association since I have been a resident in psychiatry.

4 I am a member of the Florida Psychiatric Society,
5 which is our state organization.

6 I am a member of the Tampa Psychiatric Society.

7 In addition, I'm a member of the American Board of
8 Disability Analysts, which is a society, and the American Board
9 of Forensic Examiners.

10 Q. Doctor, you have a private practice today, correct?

11 A. I do.

12 Q. Can you tell the jury about your private practice?

13 A. Sure. I have a practice in the northern suburb of Tampa.
14 Like many psychiatrists, I see people who suffer from a variety
15 of mental illnesses and substance abuse disorders. I do a lot
16 of work with depressed people. I enjoy treating that.

17 THE COURT: With which people?

18 THE WITNESS: People who have depression, depressed.

19 THE COURT: I thought he said with the press people.
20 It caught my attention. You are talking about lawyers,
21 depressed people.

22 THE WITNESS: Correct.

23 THE COURT: I am sorry for the interruption.

24 THE WITNESS: No problem. With depressed people.

25 People that suffer from clinical depression. A lot of anxiety

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KAPLAN - Direct

1 disorders. People who have panic attacks and obsessive
2 compulsive disorder. I also see outpatients who have substance
3 abuse disorders. Alcoholics, people who abuse cocaine, people
4 that abuse heroin and other narcotics, which is actually more
5 common. People who abuse prescription medications. Things
6 like that. Some of my patients are smokers, and my patients
7 that are smokers who want to stop, I certainly try to assist
8 them in stopping their smoking behavior.

9 BY MR. REILLY:

10 Q. Doctor, can you give the jury a sense of how many patients

11 you have treated in your private practice, not the
12 hospital-based practices you've already talked to us about, but
13 your private practice, there have been people who -- in
14 addition to the other treatments that they are seeking you for,
15 they have also sought assistance in dealing with smoking?

16 A. Sure. Over the years I've treated thousands of patients in
17 my outpatient practice. I currently treat about eight hundred
18 or a thousand outpatients. Of those patients, over the years,
19 I have probably treated two to three hundred patients who were
20 smokers who wanted to stop smoking. That would be just in
21 terms of outpatient experience.

22 Q. All right. Doctor, can you tell us, of the patients that
23 you treat, do you treat patients who have other kinds of
24 compulsive behavior disorders unrelated to drugs or things of
25 that nature? Just people who have compulsive behavior

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KAPLAN - Direct

1 disorders?

2 A. Sure, that's actually pretty common for psychiatrists.
3 There are groups of behaviors that cause problems in people's
4 life that involve compulsive behaviors. People that are
5 gamblers, people that are compulsive overeaters, people that
6 have compulsive buying or sexual compulsive disorders. I treat
7 people who have those kind of problems. Sometimes the term
8 "addiction" is used to describe those. They are essentially
9 compulsive behaviors that cause problems in their life.

10 Q. Doctor, do you also have, as part of your practice, a
11 forensic psychiatry practice?

12 A. I do. What that means is that I am involved in
13 medical-legal work. Probably about twenty percent of my
14 practice is focused towards that. As I sit here today, I am in
15 a tobacco-related case. I do some of that kind of work. I do
16 work as it relates to psychiatric illness. If someone suffers
17 from a disorder and they say they "can't work, I'm disabled
18 because of that," I do that kind of work.

19 I do some psychopharmacology legal work. If someone
20 is on a medication or has an illness and a crime is committed
21 as a consequence of that, sometimes people ask me to consult in
22 cases like that.

23 Q. Doctor, have you been called upon by the State of Florida
24 to testify in legal matters?

25 A. I have.

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KAPLAN - Direct

1 Q. Can you explain that kind of situation to the Court and
2 jury?

3 A. Sure. I have been involved in two cases. They were called
4 the Prozac defense trials, where someone committed a crime and
5 they were on an anti-depressant, in this case Prozac. I was
6 asked by the State of Florida to evaluate the
7 psychopharmacology of Prozac and other anti-depressants and if
8 any of their criminal behaviors were a consequence of that. I
9 have been involved in two of those cases during the last six or
10 seven years.

11 Q. Doctor, when you do that kind of work, are you compensated
12 for your time?

13 A. I am compensated for my time for any type of forensic work
14 I do.

15 Q. Can you tell the Court what your hourly rate is for that?

16 A. Sure. I charge \$300 per hour for any forensic-related
17 professional services.

18 Q. Doctor, have you ever testified in a case involving a
19 cigarette manufacturer before?

20 A. I have.
21 Q. On how many occasions?
22 A. This is my third time on the stand. So two previous
23 occasions.
24 Q. In those cases in which you have testified in legal matters
25 has your expertise been accepted by the Court in those cases?

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1 A. It has.
2 MR. REILLY: Your Honor, at this time I would tender
3 Doctor Kaplan as an expert in psychiatry and substance abuse
4 and the treatment thereof.
5 THE COURT: Okay. Not working?
6 MR. YAFFA: Not working, and no objection.
7 THE COURT: Let's see if we can get it working somehow
8 or the other here.
9 MR. YAFFA: Regardless, Your Honor. I walked up to
10 this podium. We don't have an objection as to these two areas
11 that he's being offered.
12 THE COURT: Thank you. Still, we need to get it
13 fixed. It's a brand-new system. I think they put the controls
14 in last week or the week before. The microphones and things
15 may have been a month ago.
16 Then, Doctor Kaplan is recognized as an expert in his
17 field of psychiatry and therefore entitled to express opinions
18 to you, as you understand. Mr. Reilly?
19 MR. REILLY: Thank you, Your Honor.
20 BY MR. REILLY:
21 Q. Doctor, when you are dealing with a patient who has a
22 substance abuse problem, is part of what you do to determine
23 their ability to quit whatever the substance is?
24 A. What is part of what I do?
25 Q. Yes.

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KAPLAN - Direct

1 A. I certainly want to understand why they are using
2 substances. I first want to understand if they want to stop.
3 I mean, that's incredibly important. If someone doesn't want
4 to stop, they are not going to be successful, generally. If
5 someone wants to, that certainly helps.
6 Then we want to evaluate how motivated a person is to
7 follow through with the goal of stopping and try to understand
8 their commitment. Are they willing to follow through with the
9 various types of therapies that are often helpful to help
10 people stop?
11 Q. Doctor, is that true with regard to what the substance in
12 question is?
13 A. I think that's true for any type of substance. I think
14 that's true actually for any kind of behavior. If you want to
15 change your behavior, being motivated, being committed, I
16 think, are very important qualities or characteristics.
17 Q. You sort of anticipated the question I was planning on
18 asking you, but I will get to that in a little bit.
19 How is it that psychiatrists are qualified to
20 determine somebody's motivation, their ability to quit, in
21 effect?
22 A. Psychiatry is the field of understanding how people tick,
23 so to speak; human behavior, what goes behind, why people do
24 what they do, and more importantly, if people need to make
25 changes in their behavior, if they want to, how to assist

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KAPLAN - Direct

1 people in being successful in making behavioral changes, and

2 hopefully those behavioral changes are changes that are
3 healthier for them, so to speak.
4 Q. Doctor, when you have patients that come to you who are
5 smokers, do you recommend that they quit?
6 A. Oh, sure. All of my patients who are smokers I recommend
7 to them that it would be healthy for them not to smoke. Some
8 agree and want to try to stop, and others tell me no, they're
9 going to continue to smoke.
10 Q. Can they rationally make those decisions?
11 A. Sure. I don't think that's a good decision, I don't think
12 that's a healthy decision. But people rationally decide to do
13 a lot of things that I may not think is in their best interest,
14 but for whatever reason, they decide to continue those
15 behaviors.
16 Q. Can you give us an example of other things that you
17 recommend to people that they rationally can decide not to
18 stop, but that you think are not in the best interest of them
19 from a medical standpoint?
20 A. Sure. As a physician, I am a psychiatrist, so my specialty
21 is to focus on mental illnesses and substance abuse disorders,
22 but I want my patients to be healthy. If I have a patient who
23 is overweight who has high cholesterol triglycerides, I am
24 going to try to get them to have a healthier diet, to eat
25 better things, to exercise. I certainly recommend that. In

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1 fact, I think exercise is wonderful for psychiatric illness
2 also. Sometimes they listen to me. A lot of times they don't.
3 It's their choice to decide if they want to change their
4 behavior.
5 I have patients who are compulsive gamblers.
6 Certainly not a healthy behavior. Causes problems in their
7 life financially, with their spouses, with their children. Try
8 to get them to stop. A lot of times they choose not to.
9 There are a whole bunch of different kind of behaviors
10 that we human beings do. It may not be in our best interest,
11 but that's part of being human. We can choose to do things we
12 want to if we, in our own minds and hearts, we enjoy it. That
13 is not uncommon in clinical practice.
14 Q. Doctor, I have prepared a board. Do you mind stepping
15 down?

[Witness exits the witness stand.]

16 BY MR. REILLY:

17 Q. Doctor, look at the board and tell the jury whether or not
18 those are the pleasures or benefits that people who smoke
19 appreciate or enjoy.
20 A. Yes, this is a chart that looks at the various benefits,
21 pleasures that people that are smokers have described to myself
22 and other people regarding smoking. They find the behavior
23 pleasurable. Some people feel relaxed when they smoke
24 cigarettes. A lot of people would describe the feeling of
25

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1 being less stressed, so they may smoke when they are more
2 stressed. Smoking can improve concentration, attention span.
3 Focus, that's very common. Energy, people can feel more
4 energized when they smoke, but also more relaxed. You kind of
5 feel both.
6 Socialization is a very important factor. People take
7 smoking breaks. They talk with their friends when they are
8 smoking, what was on T.V. last night, what kind of football
9 game. It's a social kind of behavior.
10 Taste, some people actually enjoy the taste and the

11 feel inside their mouth and the smell of cigarette smoke.
12 There are a variety of reasons in different people.
13 Some are more important than others.
14 Q. Doctor, I think a minute ago you were talking about the
15 principal factor in whether or not someone says they want to
16 quit smoking. What is the principal factor in determining
17 whether they will succeeded in quitting smoking?
18 A. The principal factor is do they want to stop, number one.
19 Then, if they want to stop, are they motivated to stop, are
20 they committed to follow through with a program? But the first
21 thing is are they willing to stop smoking and give up what they
22 perceive as some benefits of smoking for them.
23 Q. Can you tell the jury, if a patient indicates to you that
24 they are motivated and they are prepared to give up these
25 benefits and they have decided they want to do that, what are

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KAPLAN - Direct

1 the treatments and assistance that you have available to help
2 them quit smoking?
3 A. There are a lot of ways to help people change their smoking
4 behavior. As one example, if they are motivated, I try to
5 provide -- and this is common, this is just not myself. A lot
6 of clinicians who try to help people stop smoking do this --
7 there are behavioral methods and there are biological medical
8 methods. The Department of Health and Human Services
9 recommends that we use a combination that has your highest
10 success rate.
11 Number one, I want to support them, and I want to get
12 family members and other people to really encourage and support
13 them. Hey, you can do it. Stick with it day by day.
14 In terms of behavioral therapies, there are a whole
15 bunch. It seems like if you individualize the treatment for
16 the patient, you seem to get the best response. Some people
17 like to do relaxation exercises. You can teach them how to
18 relax their mind and their body. That's important. You can
19 teach them some self-hypnosis. Again, physical exercise, I am
20 a big fan of that. It is a great way of blowing off stress and
21 feeling better physically. Sometimes people go for hypnosis.
22 So those are various psychological therapies.
23 Sometimes support groups are really helpful. Other
24 smokers, telling people, "You can do it." That's very common
25 in any substance abuse or dependence programs. Biologic

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1 therapies, there are many different biologic therapies we can
2 offer. And pretty much nicotine replacement therapies, and you
3 can replace nicotine by various methods.
4 Since the mid '80s, nicotine has been available in
5 gum. A lot of you are familiar with that. In the '90s, we had
6 nicotine available in patches people can wear. Just recently,
7 like a month ago, there's lozenges. There is nasal and oral
8 inhalers. You can actually inhale nicotine that way. As I
9 discussed previously, that anti-depressant Zyban can also be
10 helpful in reducing craving and helping people to stop smoking.
11 To be honest, a lot of these biologic techniques have
12 not been shown to be all that effective. But again, it's
13 another piece of the puzzle and a lot of times we'll combine
14 these therapies to help people who want it.
15 Q. Doctor, is there any reason to offer any of that if their
16 patient indicates to you they have no desire in quitting
17 smoking?
18 A. Not really. If someone is unmotivated, and again, I think
19 this is true for any type of behavior that we've done a lot of

20 times in our life, that we enjoy. If someone really doesn't
21 want to stop, you can offer a bunch of these therapies and most
22 likely they are not going to be successful. In fact, most
23 people who have been successful in stopping smoking, the
24 overwhelming majority, they don't see a psychiatrist, they
25 don't see an internist. They just stop cold turkey. They

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1 don't take any medications for it.

2 MR. YAFFA: Mr. Reilly, if he is not going to be using
3 the chart, can he sit there?

4 MR. REILLY: Actually, he is going to be using some
5 other charts. I guess it's a little hard to get in and out of
6 that thing, the witness stand, so I'm happy to have him sit
7 back down, but I will have him back up in just a little bit,
8 Your Honor.

9 THE COURT: Whatever he is comfortable. That
10 microphone, the battery, is going dead on it. It goes in and
11 out occasionally. If he is through with the chart --

12 MR. REILLY: He is through with that one, Your Honor,
13 I think. We may refer to it again, I don't know.

14 THE COURT: Go ahead. Finish whatever you wish.

15 BY MR. REILLY:

16 Q. Doctor, tell the jury how important nicotine is in people's
17 smoking behavior.

18 A. Nicotine is one of the reasons why people smoke cigarettes.
19 It is just one of them. To some people it's more important.
20 In other people it's not that important. Nicotine has been
21 available in these replacement therapies for quite a long time.
22 People don't abuse or use nicotine replacement for pleasurable
23 kind of feeling. A lot of these replacement therapies have not
24 really been proven to be that helpful in the long-term of
25 smoking.

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1 THE COURT: Mr. Reilly, I think he should take the
2 stand.

3 Take the stand, please.

4 MR. REILLY: Okay.

5 [Witness resumes the witness stand.]

6 BY MR. REILLY:

7 Q. I am sorry. Had you finished your answer?

8 A. No. I just have a few more things to say.

9 Nicotine is one of the reasons why people smoke
10 cigarettes. As you can see in that chart, a lot of those
11 pleasurable feelings that people get from smoking cigarettes
12 are really unrelated, social aspects and smell and some of the
13 other pleasurable kind of feelings related to it.

14 You know, in summary, yes, nicotine is part of the
15 reason why people smoke. It's not the only reason why people
16 smoke.

17 Q. Doctor, you have already indicated that most folks quit
18 without going to a psychiatrist, but of the folks who have come
19 to you who have indicated to you that they, in fact, did want
20 to quit smoking, for those patients who have demonstrated
21 themselves to you to be motivated, what is the success rate for
22 those folks in your experience in quitting smoking?

23 A. In my clinical experience, if someone comes to me and
24 they're highly motivated, that's seventy-five percent of people
25 are successful in stopping. If someone is not that motivated,

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1 probably the opposite, about seventy-five percent of people are

2 not successful in stopping.
3 Q. Doctor, do you know how many people in the United States
4 have quit smoking?
5 A. Yes, approximately fifty million Americans, former smokers,
6 have successfully stopped smoking cigarettes.
7 Q. For good?
8 A. For good.
9 Q. Among those there have been people who smoked for a very
10 long time and a lot of cigarettes, right?
11 A. There would be people that have smoked for forty,
12 fifty-plus years and have stopped, and people that just for a
13 year or so have stopped, sure.
14 Q. Can you tell the jury how many people quit smoking every
15 year on an annual basis here in the United States?
16 A. In the United States approximately one and a half million
17 Americans will successfully quit smoking each year.
18 Q. Do you have a sense of how many or what percentage of those
19 folks quit without any assistance whatsoever?
20 A. Oh, the vast majority. Ninety plus percent of people who
21 stop smoking, actually they stop by themselves without going to
22 any groups or hypnosis or asking any clinicians for assistance.
23 Q. Can it be difficult for people to quit smoking?
24 A. Sure, sure. Stopping smoking can be very difficult for
25 some people. Not so difficult for others. Similar to other

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1 behaviors. I mean if there is a behavior that you are used to
2 that you do numerous times a day, weeks, months, years, and you
3 like it, boy, it's hard, it can be hard to change any type of
4 behavior. Cigarette smoking can be a good example of that.
5 Q. Doctor, are there withdrawal symptoms that go along with
6 quitting smoking?
7 There can be. If someone is a smoker and they stop
8 smoking, a percentage of people can develop some withdrawal
9 symptoms. The studies vary actually. Approximately
10 fifty percent of people who are smokers don't get withdrawal
11 symptoms. When people do get them, they tend to be pretty
12 mild, transient, which means they don't last very long. But
13 you can have some withdrawal symptoms, sure.
14 Q. You told this jury that you have been involved in the
15 substance abuse treatment of patients who have dealt with
16 heroin addiction, cocaine addiction, amphetamine addiction,
17 alcohol addiction. Do those come with withdrawal symptoms too?
18 A. Those can come with very serious withdrawal symptoms, sure.
19 Q. Can you give the jury a sense of the comparison of the
20 withdrawal symptoms from cigarette smoking versus the
21 withdrawal symptoms from say alcohol or heroin or cocaine,
22 things of that nature?
23 A. Sure. They are really very different. Let's start with
24 alcohol, for an example. If someone is an alcoholic, they have
25 been drinking a large amount for a period of time. We

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1 generally have to hospitalize them because the withdrawal from
2 alcohol can actually be lethal. There are several things that
3 can happen.
4 First of all, people can have seizures, grand mal
5 seizures, convulsions, and some people can die from that.
6 People can have DTs, that's called delirium tremors. Very
7 dangerous. Fifteen percent of people who have DTs actually die
8 as a consequence. What that means is that blood pressure goes
9 really high, heart rate goes high, they sweat, and they
10 hallucinate. They feel spiders, ants crawling on their body or

11 see spiders and ants crawling all over the wall. It's really
12 something. Very dangerous. We hospitalize people who are
13 alcoholics for that reason. We treat them with medications to
14 prevent that from happening.
15 Q. What kind of treatments?
16 A. There are different kinds. What they all have in common is
17 it makes it harder for a patient to have a seizure. They will
18 raise the seizure threshold. We use anti-convulsants. We use
19 tranquilizers. We use barbiturates. It makes it more
20 pleasant. They still suffer, but it makes it more pleasant and
21 they don't go through these DTs.
22 Q. I stopped you. You were just talking about alcohol. How
23 about heroin?
24 A. Heroin is not as dangerous physically, but it's nastier in
25 terms of how it feels to the patient. If someone is abusing

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1 heroin and they stop for twenty-four hours or greater, they go
2 through a very, very difficult withdrawal. Nobody dies from
3 heroin withdrawal, but it is incredibly uncomfortable. People
4 will describe almost like the feeling of someone stabbing them
5 in the stomach, a terrible abdominal cramping. People throw up
6 and have diarrhea and they sweat, and an unbelievable craving
7 for a narcotic, for heroin. This is part of the reason why we
8 see so much crime, people prostituting themselves, things like
9 that, to get heroin because the craving is so intense.
10 Cocaine is another example, especially crack cocaine.
11 People that abuse cocaine, they describe an incredible high
12 feeling. The highest high you can ever have in your life.
13 Well, there's an old saying in psychiatry: If you have a high,
14 you are going to pay for it with a down. So what happens for
15 crack cocaine abusers is after they are high, they plummet into
16 a terrible depression. Depression associated often with
17 wanting to kill yourself, suicidal thoughts. They go into
18 terrible depressive symptoms. Hard to get out of bed. Hard to
19 think. Want to kill yourself. Those are the kind of symptoms
20 we can see with crack cocaine abusers.
21 Q. Can you compare that with the withdrawals symptoms that
22 some people have when they quit smoking?
23 A. Sure. First of all, I've never in my career hospitalized
24 someone who is a smoker because of nicotine withdrawal. You
25 don't do that. People who go through nicotine withdrawal

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1 rarely miss work or loose out on going out with your wife or
2 your husband or seeing your kid's softball game, or things like
3 that. It can be uncomfortable. Generally, it tends to be more
4 on the mild side. The symptoms are different. It's more of a
5 mood symptom. People describe being a little irritable, a
6 little antsy, a little anxious.
7 Sometimes people have some difficulty sleeping. Not
8 the kind of difficulty where you are up all night long. It can
9 take you a few more hours to get to sleep. Sometimes people
10 get more hungry, sometimes people are a little less focused,
11 and sometimes people's heart rate goes down a few beats.
12 So those are possible withdrawal symptoms, although
13 again a lot of people don't have any, or if they have them,
14 they just have a few.
15 Q. Doctor, in your practice as a psychiatrist, do you use the
16 term "addiction?"
17 A. It depends. I like to use language that my patients
18 understand. In our society the term addiction is generally
19 understood by most non-psychiatrists.

20 When I am talking about this issue to a patient, I use
21 the word "addiction." But when I am talking to another
22 psychiatrist or I am dictating in a chart or things like that,
23 psychiatrists actually use the word "dependence" instead of
24 addiction.

25 Q. Is that true regardless of whether you are talking about
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1 heroin or cocaine or alcohol or nicotine or any other
2 substance?

3 A. Correct. Psychiatrists will use the term "dependence" to
4 describe any of these drugs that fulfill criteria in certain
5 people that are abusing them.

6 Q. Is nicotine in cigarettes addictive?

7 A. It depends on the definition. With certain definitions,
8 yes, it is. With other definitions, no, it's not. It depends
9 on how you are defining that term, "addiction."

10 Q. This jury has heard about the Surgeon General and
11 definitions of addiction. Could you briefly explain to this
12 jury whether or not the Surgeon General has addressed in the
13 past the issue of whether or not cigarettes and nicotine in
14 cigarettes is addicting?

15 A. The Surgeon General has addressed it several times. The
16 first time was in 1964. At that time the Surgeon General's
17 report looked at different criteria that you would say, yes,
18 this drug will fulfill; yes, it's addictive; or no, it does not
19 fulfill it; no, it is not addictive.

20 In 1964 the Surgeon General did not consider nicotine
21 in cigarettes to be addictive. That changed over the years
22 when other Surgeon General's reports came out.

23 Q. Could you explain what the change was and when it occurred?

24 A. Sure. Well, the first report they found that nicotine did
25 not fulfill certain criteria. These criteria, number one,

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1 intoxication. Intoxication means a drug makes you high. A
2 drug impairs your judgment, a drug impairs your ability to make
3 decisions. They found nicotine did not do that. They found
4 drugs like heroin and cocaine did do that.

5 They did not find that there was an overwhelming need
6 for people to have nicotine at any cost. They found that that
7 was true for other drugs.

8 They found that there was no significant psychological
9 and physiological, biological dependence on nicotine. They
10 found that was true for other drugs.

11 Finally, the fourth criteria was they didn't believe
12 that nicotine caused significant impairment to a person in
13 society, a detriment to a person in society. For example, one
14 was robbing others to get money for cigarettes. People were
15 not driving intoxicated, a car, while smoking cigarettes.

16 So for those four reasons, they called nicotine and
17 cigarette smoking more of a habit, habituation, and cocaine and
18 heroin and things like that more of an addiction.

19 Q. Did that change in 1988?

20 A. It did. The definition of addiction changed drastically.
21 It became more inclusive so that things that would not be
22 considered addictive in the past now were considered addictive.
23 The new '88 definition is a psychoactive substance, so it has
24 to affect brain chemistry, that's used compulsory, used again
25 and again. It's self-reinforcing. In other words, when you

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1 use that, you like it and you do it again.

2 Using that definition, sure, cigarettes, nicotine
3 would certainly fulfill the criteria in some people.
4 Q. Doctor, if we were still applying the criteria that the
5 Surgeon General used in 1964, would nicotine be addictive
6 today?

7 A. If we used the same criteria in '64, no, nicotine would not
8 fulfill that criteria.

9 Q. Do psychiatrists use the term "addiction," "addicting?" Do
10 they adopt the Surgeon General's definition of addiction?

11 A. No, they don't. As a society, as a group of clinicians, we
12 have used the term "dependence" instead of addiction for
13 several reasons. Number one, the term "addiction," I mean,
14 there are so many definitions. If there was a hundred people
15 and I asked everybody the definition, we would get different
16 definitions. There is not a lot of agreement when people use
17 that term.

18 The other reason was, a lot of negative connotations
19 have been associated with addiction. Is someone weak-willed?

20 COURT REPORTER: I'm sorry. Would you go a little bit
21 slower?

22 THE WITNESS: I'm sorry. That's my habit of talking
23 too fast.

24 There has been a lot of negative connotations,
25 negative feelings associated with the term addiction. For

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1 those reasons, as a specialty, we have chosen to use the term
2 "dependence" instead.

3 BY MR. REILLY:

4 Q. Doctor, is there a manual that has been published by the
5 American Psychiatric Association called the Diagnostic and
6 Statistical Manual of Mental Disorders that psychiatrists use
7 in defining things like dependence?

8 A. Yes, in fact, you are holding it.

9 Q. It's pretty clear there is one?

10 A. It's called DSM. We're in our fourth edition. It's the
11 diagnostic and statistic manual. That has the different
12 criteria that have to be fulfilled, if I am going to call
13 someone major depressant or schizophrenia or nicotine
14 dependence. In fact, I help teach the medical students at USF
15 how to use that kind of manual. It's been around for a while.

16 Q. This manual covers a heck of a lot more than just substance
17 abuse, right, or substance dependence?

18 A. Correct. All mental illnesses are in there and all
19 substance either abuse, intoxication or dependence disorders.

20 Q. My wife would tell you I'm in here somewhere.

21 Do you use this book in your practice?

22 A. Yes, I use it frequently.

23 Q. Can you tell the jury what the definition of nicotine
24 dependence is in this manual?

25 A. Sure. For a person to fulfill criteria for nicotine

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1 dependence, you have to use the substance for twelve months or
2 greater. The use of it has to cause some kind of impairment or
3 distress. Then there are seven criteria. To call someone
4 nicotine dependent or to fulfill the criteria for nicotine
5 dependence you have to have three out of seven criteria.

6 One would be when you stop or decrease smoking, do you
7 get any withdrawal symptoms.

8 Other one would be called tolerance. In other words,
9 do you need to smoke more cigarettes to get the same feeling
10 from it over time, or if you smoke the same amount, do you not

11 get the same feeling over time.
12 Number three, does a person smoke more than they
13 intended to or a larger amount than they intended to.
14 Number four, did the person have repeated thoughts of
15 quitting or having trouble quitting.
16 Then we have the use of it is impairing one's life in
17 terms of social life and educational life and occupational
18 life.
19 Finally, is the person still smoking even though they
20 have some kind of psychological or physical problem as a
21 consequence of smoking. You only need three out of those seven
22 to fulfill that criteria.
23 Q. Doctor, are there other criteria in that manual for
24 substance dependence for other kinds of substances?
25 A. There are. The criteria for dependence are similar, but

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1 then there's illnesses called substance abuse and there's
2 intoxication. Different substances have different illnesses
3 associated with them.
4 Q. Okay. I think I have another chart that compares the
5 substance dependence criteria for a number of substances.
6 Could you step down for just a minute.
7 [Witness exits the witness stand.]
8 BY MR. REILLY:
9 Q. Could you explain to the jury what that chart represents?
10 A. This is from again this manual, DSM4, and these are various
11 substances on the left here. Different types of disorders that
12 you can find. This is dependence. We just talked about that.
13 Abuse, intoxication and withdrawal. This compares different
14 substances, including caffeine found in coffee. It compares
15 whether they will have different diagnosis.
16 Q. Doctor, is there something common to all of them except
17 nicotine?
18 A. There is. The difference is, as you see from nicotine, you
19 can have a dependence diagnosis and you can have withdrawal.
20 You don't see abuse. The big difference I think clinically is
21 you don't see intoxication. In other words, all of these drugs
22 can intoxicate a person. It can make you high. It can impair
23 your judgment. It can impair your ability to think, make
24 decisions.
25 Nicotine does not do that. In fact, quite the

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1 opposite. There has been some research for Alzheimer's
2 patients using nicotine to help improve focus and
3 concentration. That's the big difference between these
4 different drugs.
5 Q. I think that chart indicates that there are withdrawal
6 symptoms associated with those substances, right?
7 A. With some of the substances, yes.
8 Q. Does that mean that the withdrawal symptoms are the same
9 for other substances?
10 A. No, they are different. As we discussed previously, the
11 symptoms, the severity, the possible medical complications of
12 different withdrawal syndromes can vary tremendously. Again,
13 for nicotine it tends to be mild, tends to be kind of
14 short-term.
15 Q. Doctor, I am going to let you resume your seat.
16 [Witness resumes the witness stand.]
17 BY MR. REILLY:
18 Q. Doctor, can you have withdrawal symptoms from behavioral
19 changes, from non-substance situations?

20 A. You can. Any type of behavior that we like to do and that
21 we do with some frequency, if you ask a person to stop it and
22 they get some pleasure out of behavior, it is not uncommon for
23 people to develop withdrawal-like symptoms.

24 I'll give you an example. Let's say someone goes on a
25 diet and you are used to eating fatty foods and steaks and this
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1 and that, and you really enjoy ice cream, and you put someone
2 on a restrictive diet, which is common for a lot of us. Diets
3 are pretty common. You talk to family members and they will
4 tell you, "Wow, stay away from her, stay away from him. He is
5 irritable and he is antsy and he is not sleeping."

6 I don't know if I'd call them withdrawal symptoms. We
7 can use that term. But the point is, if you are doing
8 something repetitively, you're used to it, you like it, and
9 then you are asked to stop it, it is not uncommon for people to
10 develop changes in their mood. We can call it withdrawal
11 symptoms or not, but the point is, it doesn't feel good. You
12 miss what you were doing. So people have different reactions
13 to that.

14 Q. Doctor, we had on the board here just a minute ago these
15 various substance dependences. As a psychiatrist, when you
16 treat people for their substance dependences, does the
17 treatment vary depending upon what the substance is?

18 A. Oh, it varies tremendously. In common, you want to teach
19 people behavioral ways to change their behavior. But the
20 medications we use can vary. Of course, for the withdrawal
21 symptoms I am going to have to hospitalize some people because
22 of the dangerousness. For some types of disorders I really
23 need to get people out of their environment so that they are
24 not going to be exposed.

25 If you have a person who abuses crack cocaine, you
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1 have to get them away from the environment where they could
2 actually get a hold of that. Same thing for heroin too. You
3 really need some time away from their ability to get that
4 substance if you are going to be successful in your treatment.

5 Q. Doctor, how do you assist someone who indicates to you that
6 they actually want to quit smoking as opposed to someone who
7 tells you that no, they are not interested, they enjoy smoking,
8 and they don't want to quit smoking? What do you do for
9 somebody who comes to you and says, "Yes, I am prepared. I do
10 want to quit smoking. I am ready to give up those pleasures
11 that you talked about?"

12 A. Sure. If they want help, I'm certainly going to try to
13 help them. Again, I try to individualize plans as much as
14 possible.

15 Number one, I'm going to educate them. What are some
16 of the benefits of them stopping smoking? In my clinical
17 experience actually, as people know this already, they know the
18 health risks of smoking cigarettes. But still, I'm going to
19 re-educate them. Let me encourage them as much as possible to
20 want to change. Again, usually they are already at that point,
21 if I am going to be having this kind of conversation.

22 I am going to provide therapy. I am going to provide
23 support. I am going to try to get family members, loved ones,
24 significant others, to try to be part of what we're doing to
25 help people stop.

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1 THE COURT: Doctor, I am sorry to interrupt you. You

2 are talking now about you're going to provide therapy and
3 support. Then you are going to go to family members and get
4 them do that; is that right?

5 THE WITNESS: That's correct.

6 THE COURT: When you go to the next group, could you
7 talk a little slower

8 MR. REILLY: Sorry, Your Honor.

9 THE COURT: He can't help it. It's a compulsion. He
10 has got to talk to one of his colleagues about this one of
11 these days.

12 MR. REILLY: If I could think that fast.

13 THE COURT: I'm sorry. It's just your normal way of
14 speaking, and that's fine. We are trying to make a record
15 here, and it's a little hard because you do speak rapidly. And
16 we all comprehend what you are saying, but if you could slow it
17 down, we can get a better record.

18 Where we left off, the question was, what do you do to
19 help somebody that really wants to quit. You talked about
20 educating them and going to your family. That's where I
21 interrupted you.

22 THE WITNESS: I will certainly try to talk slower.

23 What I am going to do next is I am going to provide
24 behavioral therapies. I am going to offer different ones. And
25 to be honest, I am going to try to find one that fits that

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1 person. Some of them we talked about. I am going to teach
2 them some self-hypnosis techniques. I'm going to teach them
3 some self-relaxation techniques. I'm going to try to get them
4 motivated for some kind of physical exercise. If there is a
5 local support group, I'm going to try to get them involved in
6 that. People will not do all of these, but I am going to try
7 to find the ones that people are willing to try.

8 Then I may also use some nicotine replacement
9 therapies. What I usually do is a combination of Zyban, which
10 is that anti-depressant that you prescribe that can reduce
11 cravings in some people. In addition to that, I usually use
12 the nasal inhaler, which is kind of the closest you can get to
13 smoking a cigarette, in terms of getting nicotine in and levels
14 decreasing. So I usually use a combination of those
15 techniques.

16 BY MR. REILLY:

17 Q. Doctor, I would like to ask you one other thing, and then
18 if it's appropriate, Your Honor, to break for the noon break.

19 If you have someone who is a heroin addict, what kind
20 of treatment do you provide for them?

21 A. It's going to be very different. If someone is a heroin
22 addict, I am going to need to hospitalize them, usually, to get
23 them away from heroin because they are going to find a way of
24 getting it if they're quote, addicted, or dependent on heroin.

25 I'm going to give them medications to block the

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1 withdrawal. I am going to give them medications that bind to
2 the same receptors as heroin does to reduce the withdrawal.
3 And I am going to get them very involved in 12-step, NA,
4 Narcotics Anonymous, therapies so that they have a lot of
5 support, they have a kind of a game plan, a way of addressing
6 their daily craving for heroin.

7 Q. A much different situation?

8 A. Much different in terms of the intensity, in terms of the
9 kind of therapies you need to use. Very different.

10 MR. REILLY: Your Honor, this would be a good spot.

11 THE COURT: Ladies and gentlemen, we will take the
12 noon recess at this time, and ask that you return this
13 afternoon at 1:15, I guess, given our schedule. Later on we
14 are going to let you go home early. We have got some matters
15 we are going to take up. We will resume at 1:15 after the
16 lunch recess. Thank you very much.

17 [The jury leaves, the courtroom.]

18 THE COURT: Doctor Kaplan, we are in the middle of
19 your testimony, so we ask that you not discuss your testimony
20 with any of the lawyers or staff people. Certainly, you can
21 talk to them about where to go to lunch or whatever, but as far
22 as your testimony and all of that, we ask that you not discuss
23 that.

24 Maybe to help the doctor -- help do this a little bit
25 slower, maybe you could pause after he finishes an answer

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1 before you start with your next question. We don't need this
2 on the record.

3 THE COURT: Thank you, gentlemen.

4 [Morning proceedings concluded at 12:15 p.m.]

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7

C E R T I F I C A T E

8

I hereby certify that the foregoing is an accurate
9 transcription of proceedings in the above-entitled matter.

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DATE

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